MR.SPOT® Processor

REF 726100

CE

User Manual

Version: 7 / 2013 Changes to version 6 /2013 highlighted in yellow.

IT IS IMPORTANT TO READ THIS MANUAL BEFORE USING THE MR.SPOT® PROCESSOR

Please read this manual carefully before using the MR.SPOT® Processor and make it accessible to all users. Failure to comply with the instructions in this manual will void the manufacturer's warranty and may pose a risk to the user.

Ensure all users are conversant with the instrument – contact BAG Health Care GmbH for any further instrument or training requirements if in any doubt before using the instrument.

Consult User Manual where symbol (left) is seen on the instrument.

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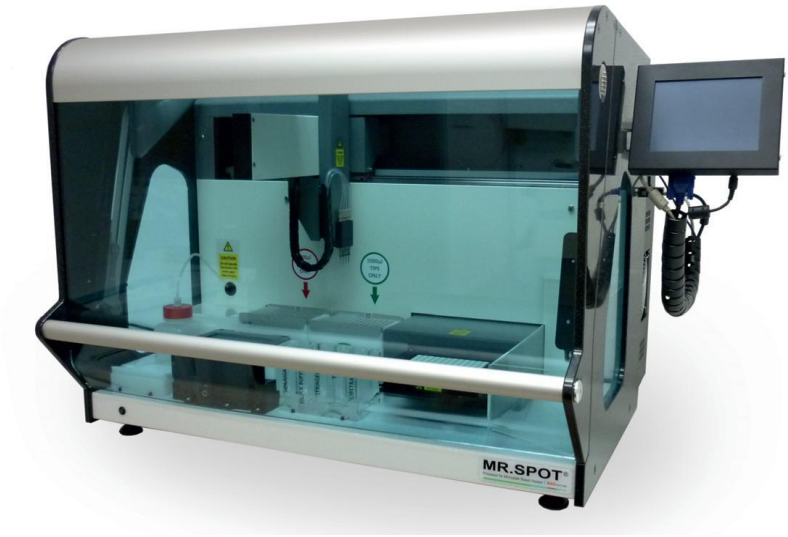
1 INTRODUCTION



The MR.SPOT® Processor is a bench top automated system for processing microplate-based assays.

The MR.SPOT® Processor is designed for use with reverse dot blot array assays, and provides full automation for the washing and hybridisation steps, including pre-heating of the PCR plate.

The arrays are pre printed onto microplate wells held on a platform within the MR.SPOT® Processor, and the whole detection assay is performed within the wells. The microplate well holder offers heating and cooling under a bespoke peltier controlled system, giving precise temperature control during the assay, as well as mixing of the wells during incubation. An X Y Z mechanism has a tip picking and ejection system for sample handling, and reagent addition. Precise volume control is achieved using peristaltic pumps, driven by micro stepping motors under software control. Incorporated into the tip picking system are 4 aspirating needles, for the removal of waste reagent, and are connected to a peristaltic pump. The minimum number of samples that can be processed during a run is 1 and the maximum is 96. A high-resolution camera is an integral part of the MR.SPOT® Processor, where the microplate wells move into a scanning chamber for image capture at the end of the assay.

The base of the instrument has positions for a disposable tip holder, hybridisation trough with pre-heating, PCR plate holder with pre-heating, 5 position reagent holder, priming trough, and tip waste container.

The MR.SPOT®Processor operator interface is via an integral touch screen. The touch screen also provides visual feedback outlining the progress of the assay. The MR.SPOT® Processor has a built in PC for communicating with an external PC for image transfer and analysis with the interpretation software. The PC also houses the embedded software for controlling the MR.SPOT® Processor electronics.

2 TECHNICAL SPECIFICATIONS

Instrument type:	Stand alone bench top
Processing Capability:	1 to 96 samples per run
Processing Time:	Typically 2hrs 20 minutes for 96 samples
Temperature Control:	Peltier under software control
Processing Volumes:	50 µl to 300 µl
Dispensing Mode & Accuracy:	Peristaltic pumps: +0 / - 10%
Software:	Embedded software
Voltage & Frequency:	Electrical power source at AC 100-240 V, 500 W and 50/60 Hz
Fuses	5A UL Approved – Ø5x20 mm
Dimensions:	600(H) x 620(D) x 780(W) mm
Weight:	60 kg
Consumption value (energy)	350 W (max)
Acoustic noise level (dB)	~ 60 dB
Electromagnetic emissions	Class A 30 MHz to 1000 MHz
Radiated field immunity	10 V/m 80 MHz to 1000 MHz 3V/m 1.4 GHz to 2 GHz 1V/m 2 GHz to 2.7 GHz

3 UNPACKING AND INSTALLATION

3.1 Unpacking

CAUTION: HEAVY INSTRUMENT
At least two people are required to move the carton, to unpack, and to lift the instrument from the carton and position on the bench. The instrument weighs 60 kg and the whole unopened carton may weigh as much as 95 kg.

Visually inspect the container for transit damage and check the transport indicators.

Place the carton in an upright position to open.

The instrument is packed in a re-usable container, which may be collapsed for storage. It is recommended that appropriate gloves be worn for unpacking; some components of the container may have sharp edges.

Remove the outer straps and lift off the main cover. Remove all accessories.

Lift the wooden outer shell upwards and place to one side.

Two people are required to lift the instrument off the base, one positioned at the front of the instrument, and one person positioned at the back of the instrument. Lift one side of the instrument and at the same time remove the foam side cheek and gently rest the instrument down, repeat this procedure for the other side of the instrument. Remove any protective bubble wrap, and foam top protectors. Remove accessory box from top of instrument.

The outer shell can be collapsed flat and placed onto the base of the packaging and the lid re-placed over it. Please store container in a safe place.

Inspect the instrument for any obvious signs of transit damage.

Report any damage immediately to your local representative.

Check that the serial number on the instrument and the delivery note are the same.

Check that all accessories are present. Contents should be as follows:

1x	Touch Screen
1x	Touch Screen VGA Cable
1x	Touch Screen USB Cable
1x	Touch Screen Mounting arm and screws and tools
1x	Spare fuses 5A (pack of 2)
1x	Reagent Trough
1x	250 ml D.I. Water Bottle
1x	250 ml square bottle for wash solution
1x	Bottle Holder
1x	Tip Rack Holder
1x	Waste Tip Basket
1x	Priming/Waste Trough with Lid
1x	Hybridisation Trough
1x	Mains Lead
1x	Barcode reader
1x	User Manual on CD
1x	Set of dummy test strips with 16 single clear wells
1x	Installation CD for HISTO MATCH Software
1x	Spare Set of 4 O-rings
1x	Silicone grease syringe

3.2 Environmental Conditions

3.2.1 Bench Space

Always place the MR.SPOT® Processor on a solid flat surface. Place the instrument so that there is no obstruction to the Touch Screen on the right hand side of the instrument. The **minimum** bench space required is 1000 mm width and 700 mm depth – the depth should be 700 mm if there is to be no overhang of the front of the instrument.

Place the instrument a maximum of 1 metre from an appropriate power source. The coverlid swings upwards, so that when at its maximum opening the height from the instrument base to the extreme of the lid is 1000 mm.

3.2.2 Disconnection guidelines

In an emergency immediately turn the power off and unplug from power source.
The mains switch and mains lead connection is located on the left hand side panel of the instrument. Do not place the instrument too close to any object that might impair emergency disconnection in an emergency, particularly any object to the left side panel of the instrument.

3.2.3 Ventilation

Do not place the instrument in line with a direct draft such as an air vent. Otherwise there are no specific ventilation requirements for the instrument. Allow a space of 100 mm between the instrument and any wall or other instruments.

3.2.4 General

Keep free of dust, harsh solvents and acidic vapours. Vibration and harsh sunlight must be avoided to ensure correct results. The MR.SPOT® Processor should always be placed on a flat stable surface. The MR.SPOT® Processor is intended for **indoor use only** and should not be subjected to unduly large variations in temperature and humidity. This instrument was designed for use in a typical laboratory environment, i.e.:

Altitude:	Up to 2000 m
Temperature:	Ambient temperature range: Between 15…30°C
Humidity:	Maximum relative humidity 80%
Mains voltage:	100-240V

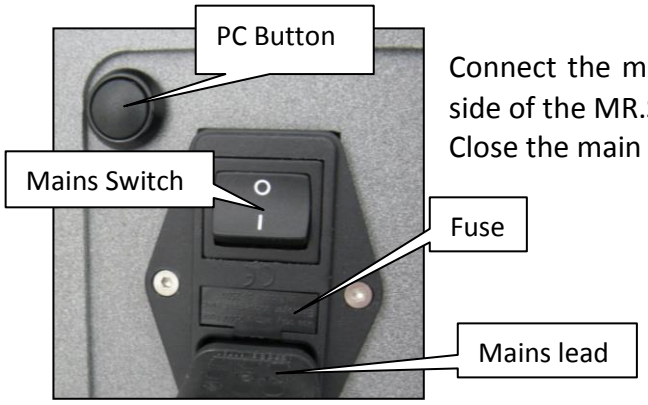
Leave to stand for 3 hours before applying power to avoid problems that might arise from condensation.

Storage conditions: from 5°C to 50°C

3.3 Initial Setup

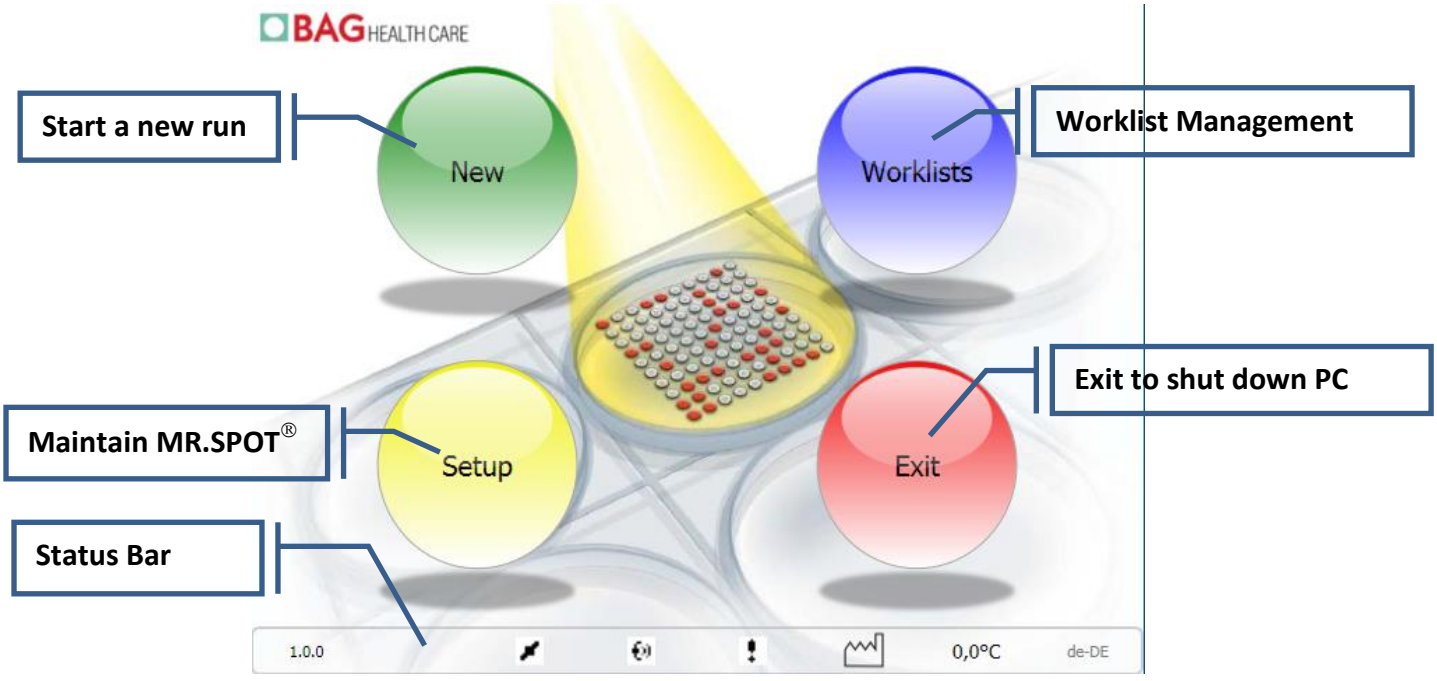
After unpacking according to **3.1** above, place instrument on a bench according to **3.2** above.

Attach the touch screen using the support arm provided, and connect to the MR.SPOT® Processor with the associated cables.



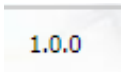
Connect the mains lead to the mains lead socket on the left hand side of the MR.SPOT® Processor.
Close the main door. Switch 'On' the mains switch.

A number of initialization routines will automatically start. The 'Z' axis will move upwards to the HOME position, the 'Y' axis will move to the HOME position, the 'X' axis will move to the HOME position. The reaction plate holder will move outwards from the incubation chamber.
The following screen will appear on the Touch Screen.



3.4 Status Bar

In the status bar at the bottom of the screen the following information is displayed:



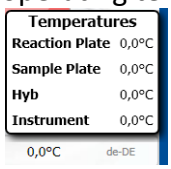
Software version number: clicking on the version number opens a log file (see chapter 8.6 Error messages)

MR.SPOT® status (see below: Status icons)

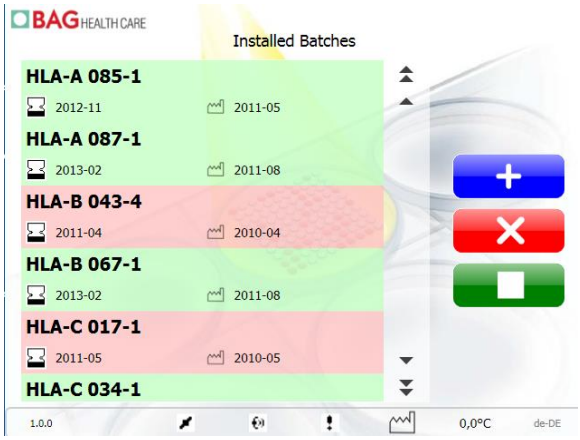
Broadcasting events on network

Door guard disabled

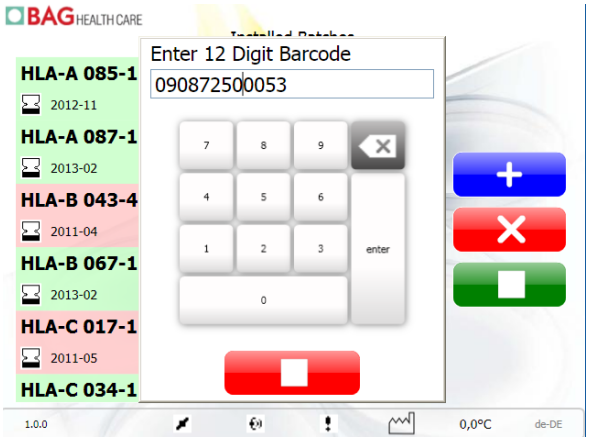
Temperature of the reaction plate. Clicking here opens a window displaying various operating temperatures.



Installed batches: clicking on the symbol opens a window with the installed batches:



Expired batches are have a red background, those not expired a green one.
Batches can be deleted by highlighting them and pressing the **Delete** button.



Batches can be added by pressing the **Add** button and entering the 12 digit barcode (on the label for the test strips) with the onscreen keyboard. Then press enter on the keyboard.

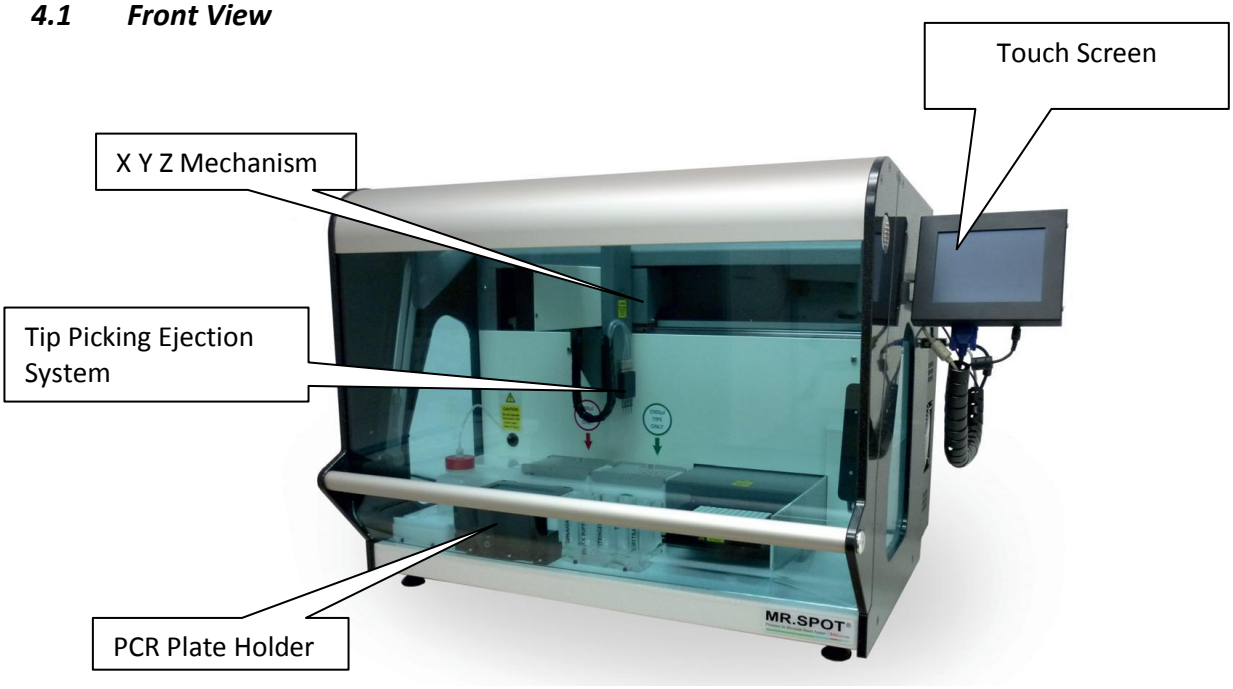
The button will close the window.

MR.SPOT® status icons:

	Disconnected		Paused
	Connected		Running
	Initializing		Stopped
	Pausing		Imaging

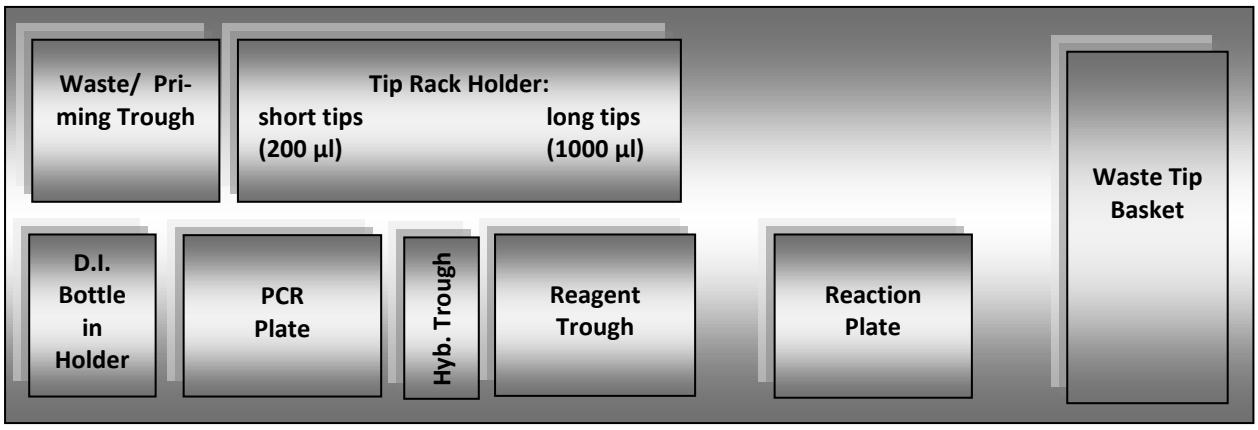
4 SYSTEM OVERVIEW

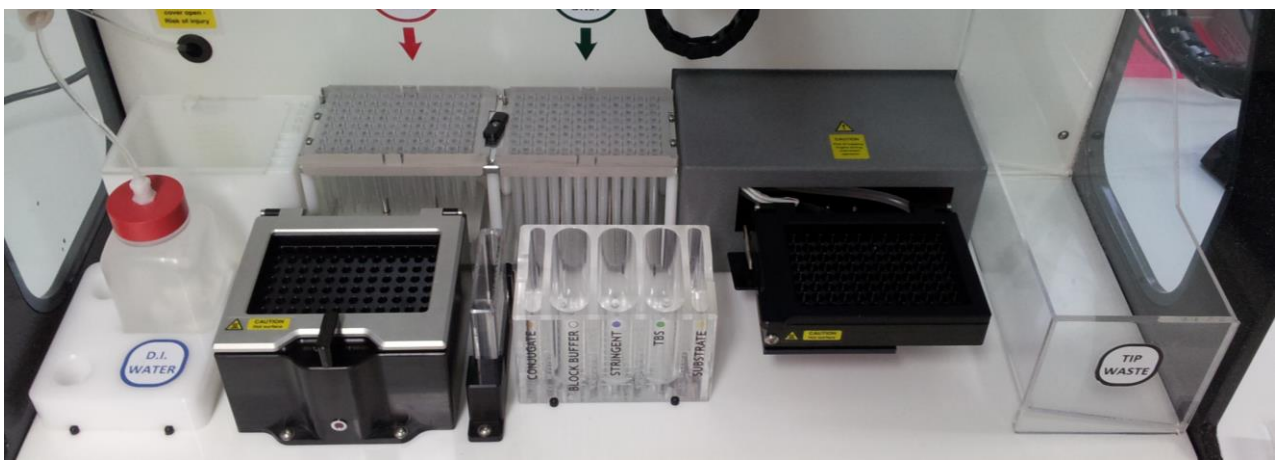
4.1 Front View



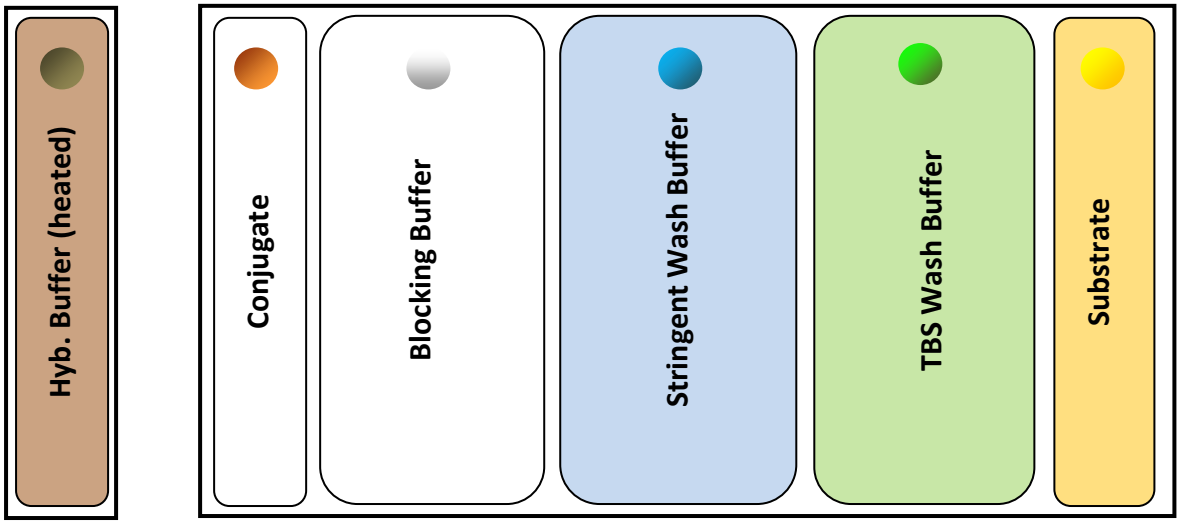
4.2 MR.SPOT® Processor Base Layout

Position the accessories on the base as outlined below.





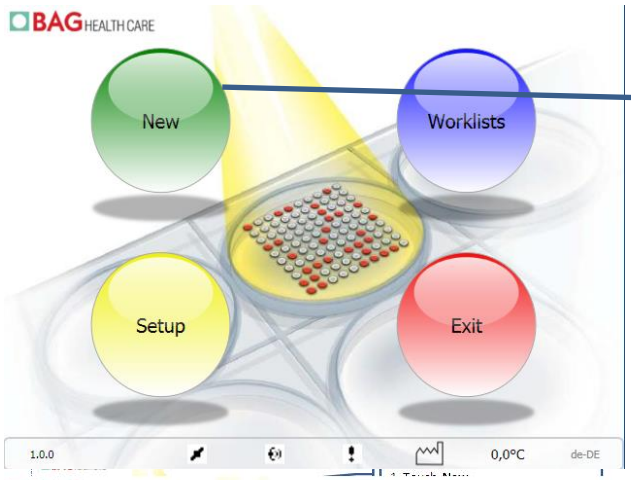
Reagent Position in the Reagent Trough:



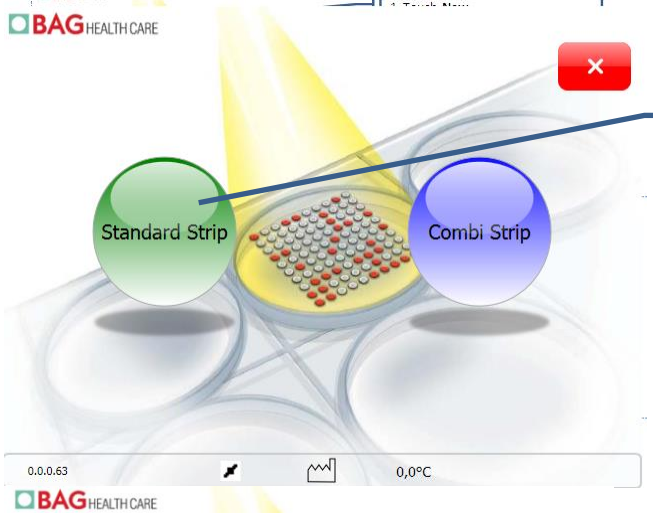
4.3 Preliminary Test

D.I. Water Bottle	Insert the clear tubing into the water bottle.
Waste / Priming Trough	Ensure that the waste / priming trough is empty and located in position.
Tip Rack Holder	Locate the tip rack holder on the base. Be careful to load the short tips (200 µl) in the left and the long tips (1000 µl) the right position. First insert the tip racks under the screws at the sides of the holder. Then close the switch in the middle to secure them in position.
Hybridisation Trough	Position the Hybridisation Trough. The Hybridisation Trough holder is heated. Take care if removing the Hybridisation Trough from its holder before the end of the assay. Risk of Injury.
PCR Plate Holder	Place the PCR plate into the PCR plate holder, and close the lid. Take care if removing the PCR plate from its holder before the end of the assay. Risk of Injury. When the red LED is on, it indicates that the PCR plate is being heated. At the end of the heating step, the red LED will flash continuously indicating that the PCR plate holder is still too hot to touch.
Reagent Trough	Position the Reagent Trough.
Test wells	Place number of wells to be processed into the reaction plate holder. Ensure that these are placed firmly in place, and ensure that the reaction plate lid is closed. For the preliminary run one strip is sufficient.
Tip Collecting Basket	Ensure that the Tip collecting Basket is located and empty.

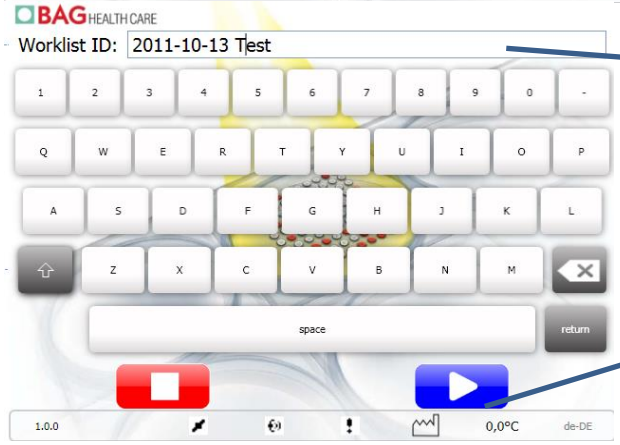
Once the reagent throughs have been set up, proceed to run a short test assay using D.I. Water. Follow the commands indicated below.



1. Touch **New.**

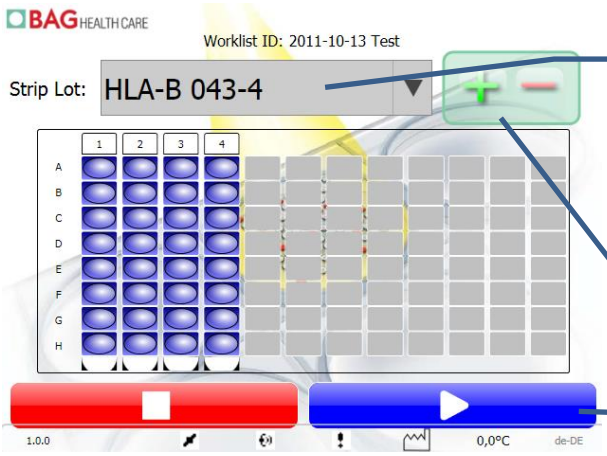


2.Chose **Standard Strip.**



3. Use keyboard to enter Work-list ID.

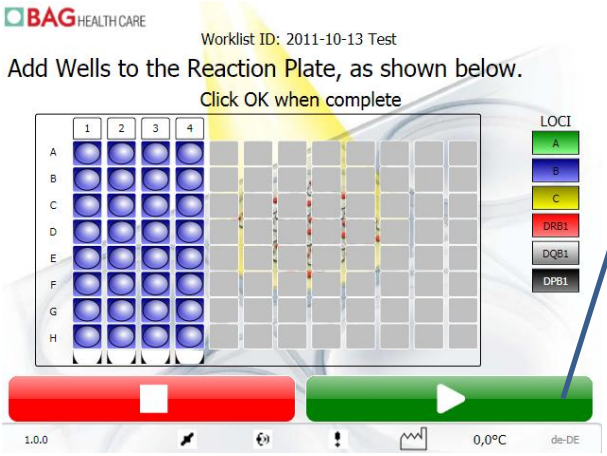
4. Touch **Next.**



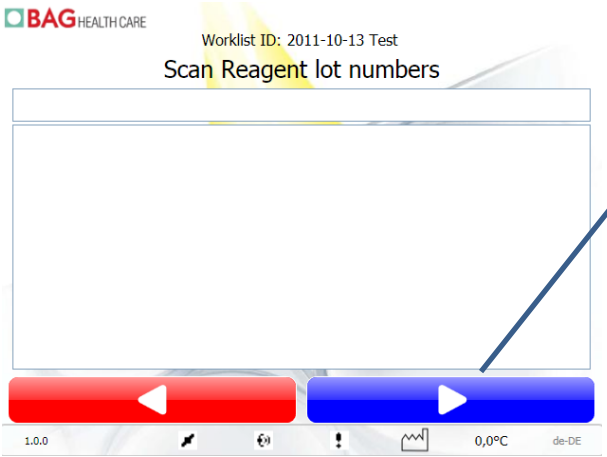
5. Chose any lot from the drop-down list.

6. Touch the **Add Strip** button.

7. Touch **Next.**



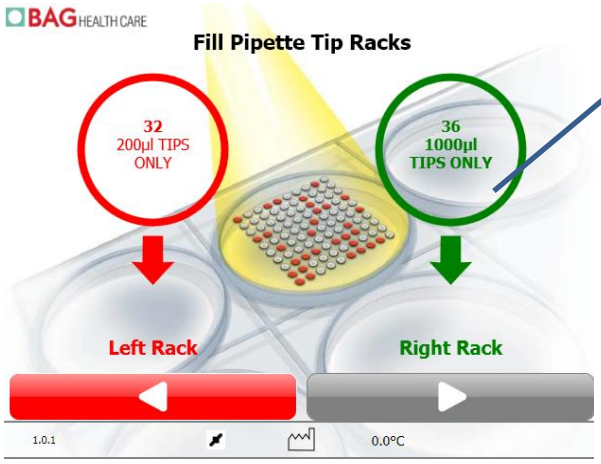
8. Add four dummy test strips and press **Next**.



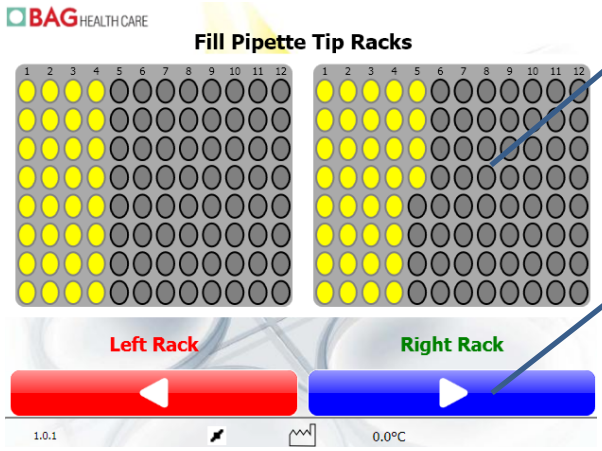
9. You do not need reagent lot numbers for the preliminary run. Simply press **Next**.

10. Confirm each item on the check list. Use D.I. Water instead of the reagents and dummy test strips.

11. Press **Next.**

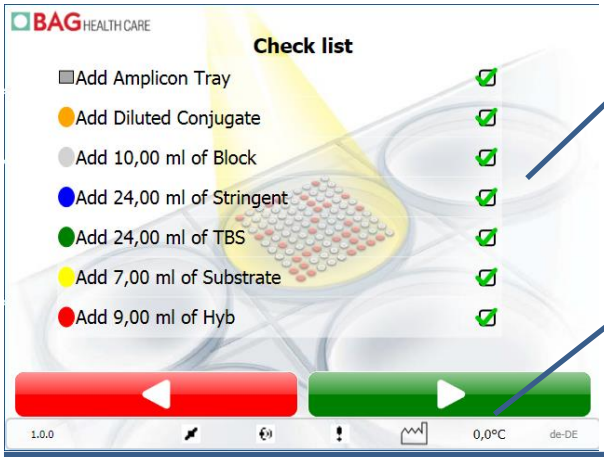


12. Fill in the indicated number of tips and confirm each item on the check list.



13. Confirming will show the correct layout of the required tips.

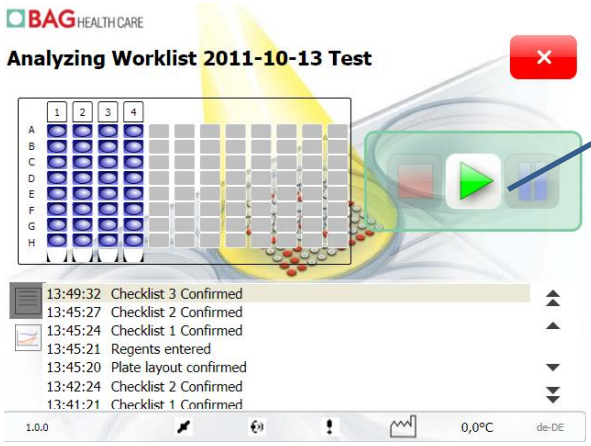
14. Press **Next.**



15. Confirm each item on the check list.

16. Press **Next.**

17. Close the door of the instrument. Note that the instrument is only running with the door closed. Opening the door during the run will interrupt the assay. It is possible to resume the run after closing the door again.



18. Press the **Start** button.

Observe the operation of the instrument, and ensure that the following are functioning correctly:

(1) Priming – The instrument will move above the waste / priming trough to prime each line by dispensing D.I. Water into the waste / priming trough.

(2) The reaction plate holder will move out of the incubation chamber.

(3) The tip picking / ejection mechanism will pick up a set of 4 tips. Ensure that the tips are picked up and remain attached to the mechanism.

(4) The X Y Z mechanism will move above the reagent trough and aspirate D.I. Water.

(5) The aspirated volume will then be dispensed to the test wells. For dispensing reagent, the reaction plate holder will remain level.

(6) The X Y Z mechanism will move to above the tip collection basket, and eject all 4 tips. Ensure that all 4 tips are ejected at this point.

(7) The PCR Heater LED should be ON.

(8) The reaction plate will shake for the first incubation step (5 min).

(9) For aspiration of the spent reagent, the reaction plate will tilt. Ensure that the aspirating needles aspirate from the edge of the well, to avoid touching the array.

(10) After this step you can abort the run.

If no problems are noticed or reported by the instrument, the instrument can be used to run an assay.

5 CONSUMABLES

The MR.SPOT® Processor has been designed for use with specific disposable tips, supplied by the manufacturer (BAG Health Care GmbH, REF 726099, HISTO SPOT® Pipette Tips, 1000 µl and REF 726097, HISTO SPOT® Pipetting Tips, 200 µl) or your distributor. Do NOT attempt to use any other tips. This could result in the failure of the instrument to perform correctly.

6 SAFETY & GENERAL INFORMATION

6.1 Instrument labelling

Please observe and respect all caution labels shown on instrument & consumables:

6.2 Detailed Personal Safety Information

The Heater Plate of the PCR plate holder can reach temperatures of 100°C during a run. Take care not to touch the heater plate, particularly if the heater LED is on or flashing.

Avoid touching the MR.SPOT® Processor with wet hands, and DO NOT attempt to disassemble the MR.SPOT® Processor. In either case electrical shock may result, and in both cases the warranty will be invalidated.

The MR.SPOT® Processor will automatically stop when the cover is opened. Never attempt to manipulate or run the instrument with the cover opened.

It is recommended to wear eye protection, a laboratory coat and protective gloves when operating the instrument / handling reagents. If contact of any reagent occurs with skin or eyes, wash thoroughly with water.

6.3 Cleaning & Disposal

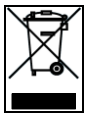
Cleaning of the MR.SPOT® Processor should be performed regularly using proprietary decontaminants followed by water and appropriate detergent.

ALWAYS wear protective gloves prior to cleaning.
Use an appropriate detergent to clean surrounding surfaces.
Use a cloth, dampened in detergent and wipe all areas in and around the base and the reagent area. Use the same technique to wash all parts that may come in contact with any accidental spillage.

The instrument will automatically clean all the lines with D.I. Water during the assay. Clean all the reagent troughs at the end of each run, and ensure that the priming trough is emptied and the tip-collecting basket is also emptied.

DISPOSAL:
Dispose of any unused reagents and waste in accordance with country, federal, state and local regulations.

Instrument Disposal:



As part of the WEEE EU directives, this instrument should be returned to the manufacturer for dismantling at the end of its life.

7 INSTRUMENT OPERATION

7.1 Running the Assay

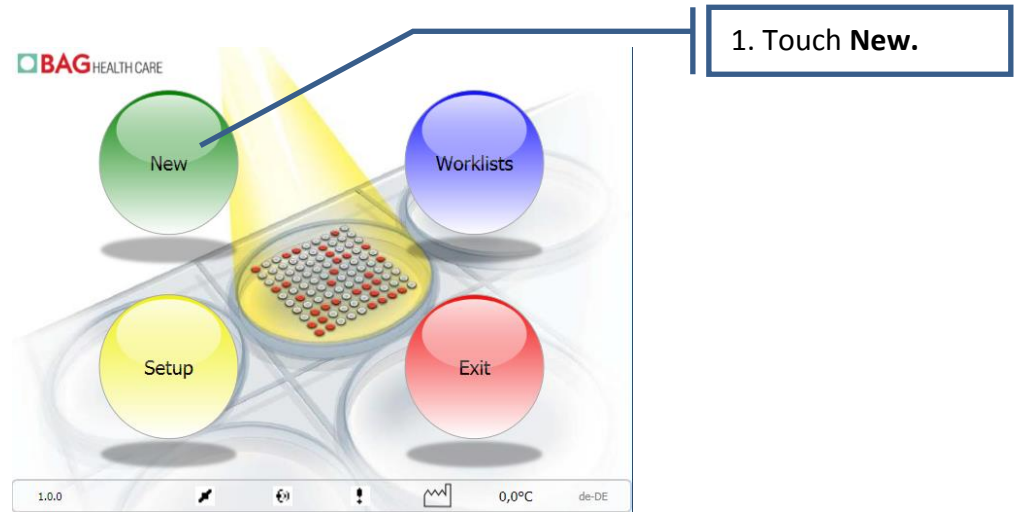
Connect the mains lead to the mains lead socket on the left hand side of the MR.SPOT® Processor.

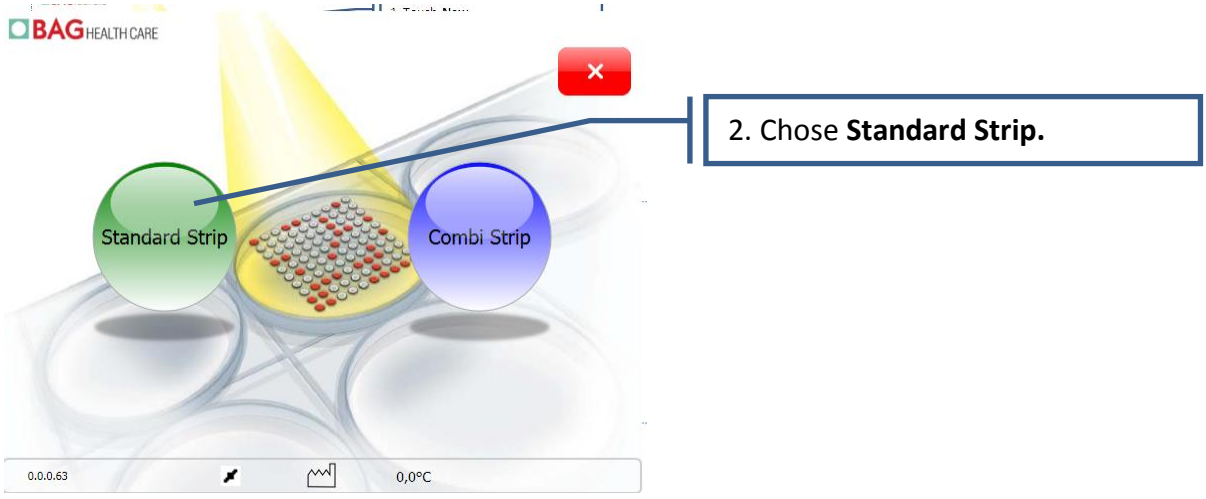
Close the main door. Switch 'On' the mains switch.

Ensure that the accessories required to run the assay have been set up correctly on the instruments base before proceeding with the assay. Refer to 4.2 MR.SPOT(Processor Base Layout).

A number of initialization routines will automatically start. The Z axis will move upwards to the HOME position, the Y axis will move to the HOME position, the X axis will move to the HOME position. The reaction plate holder will move outwards from the incubation chamber. The following screen will appear on the Touch Screen. Follow the commands indicated below.

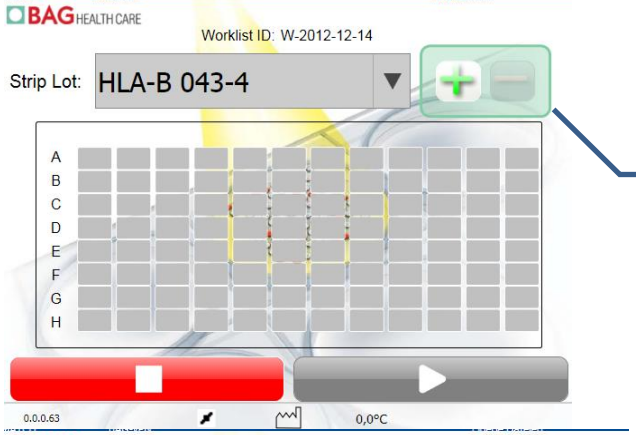
7.1.1 Creating a new standard worklist



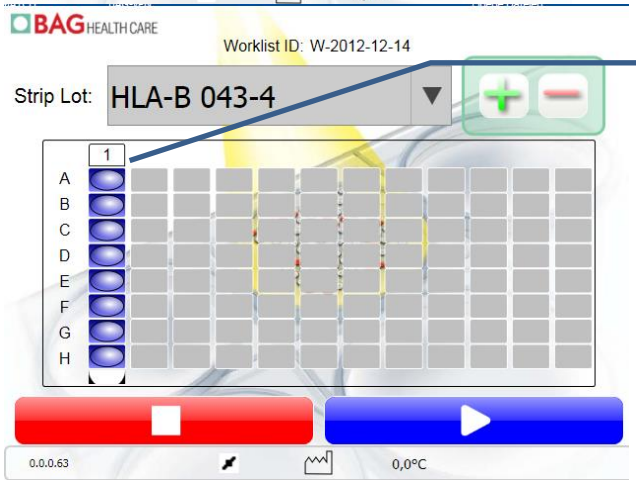


3. Use keyboard to enter Worklist ID.

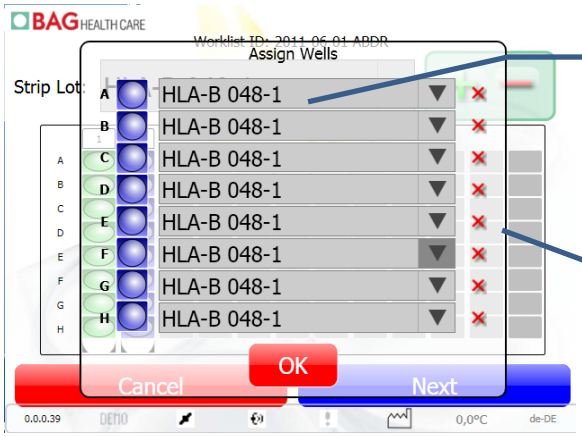
4. Touch **Next.**



5. You can enter a strip directly by reading the barcode. Alternatively you can chose a lot from the dropdown list and touch the **Add Strip** button.

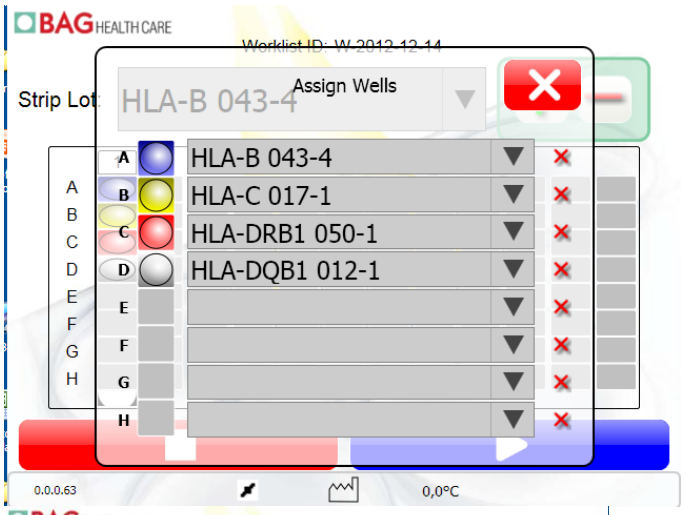


6. You can edit single wells in a strip by clicking on the numbers at the top.



7. Enter the strip lot number for single wells by using the barcode reader, or by choosing one from the dropdown list.

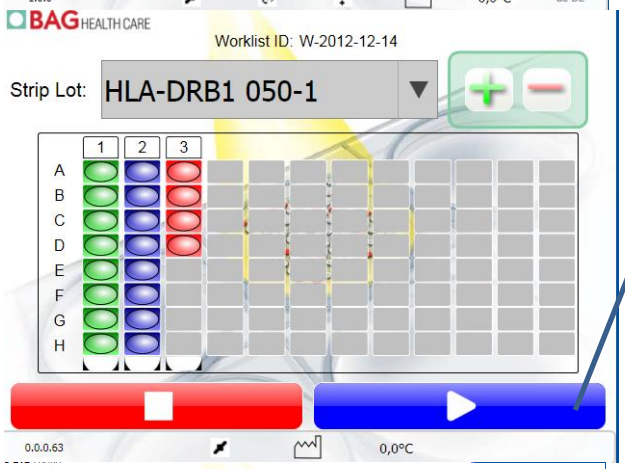
8. Clicking on the red cross deletes a well. You have to add dummy wells there.



It is possible to choose any layout for test.

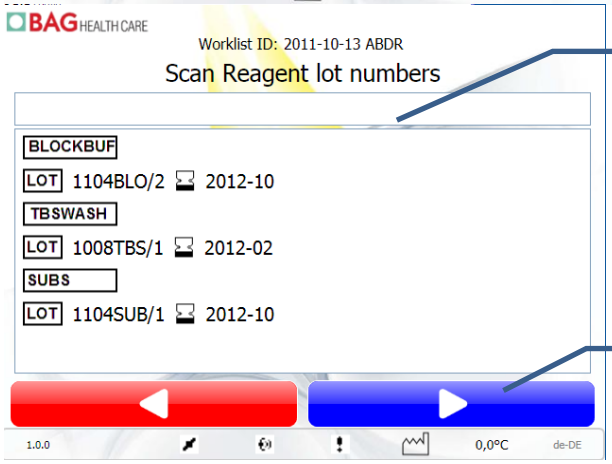
You have to add clear dummy wells to reach multiples of four for the number of wells!!!

9. The software validates the worklist and gives an error message if there are any problems.



10. Add the test strips as shown in the screen.

11. Touch **Next.**

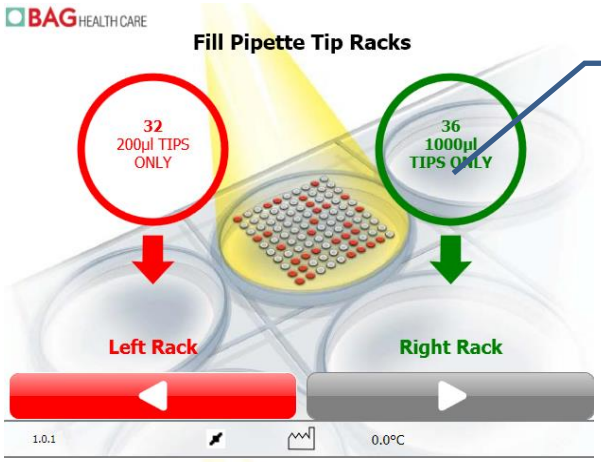


12. Use the barcode reader to enter the reagent lot numbers.

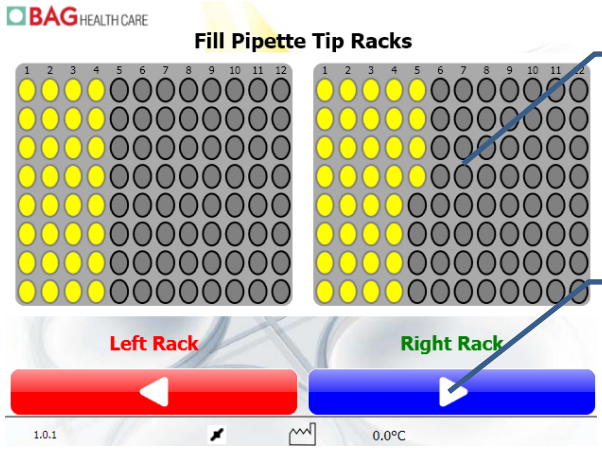
13. Press **Next.**

14. Confirm each item on the check list.

15. Press **Next.**

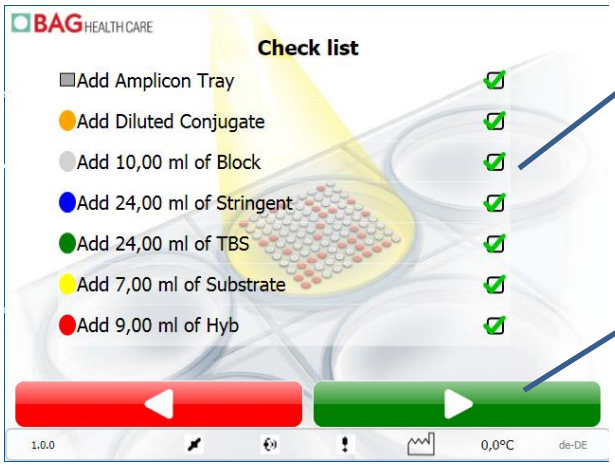


16. Fill in the indicated number of tips and confirm each item on the check list.



17. Confirming will show the correct layout of the required tips.

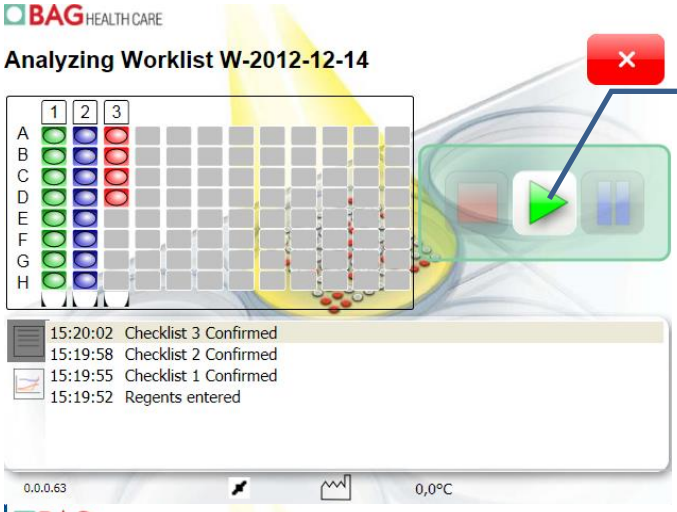
18. Press **Next.**



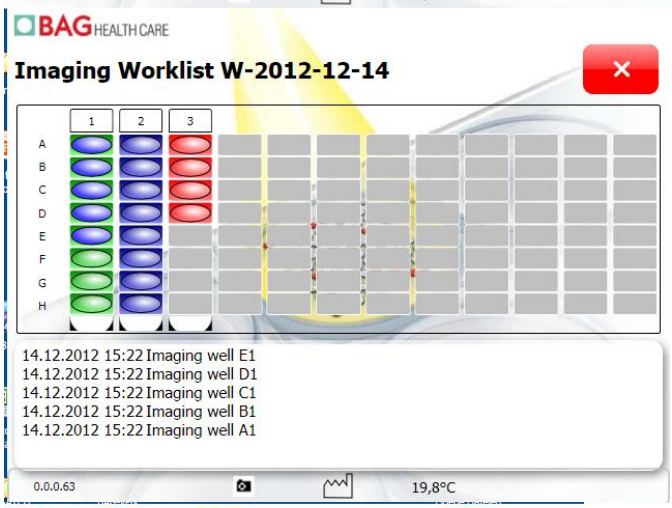
19. Confirm each item on the check list.

20. Press **Next.**

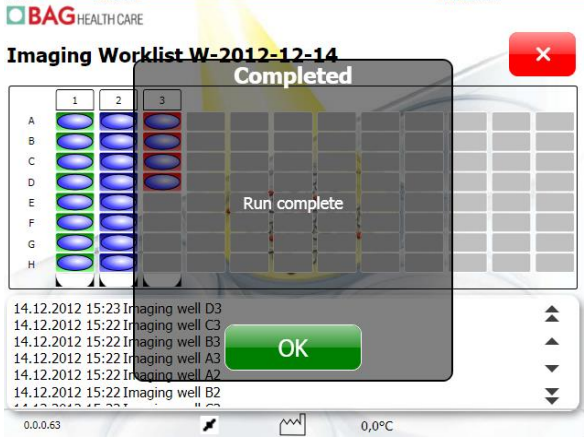
21. Close the door of the instrument. Note that the instrument is only running with the door closed. Opening the door during the run will interrupt the assay. It is possible to resume the run after closing the door again.



22. Press the **Start** button.

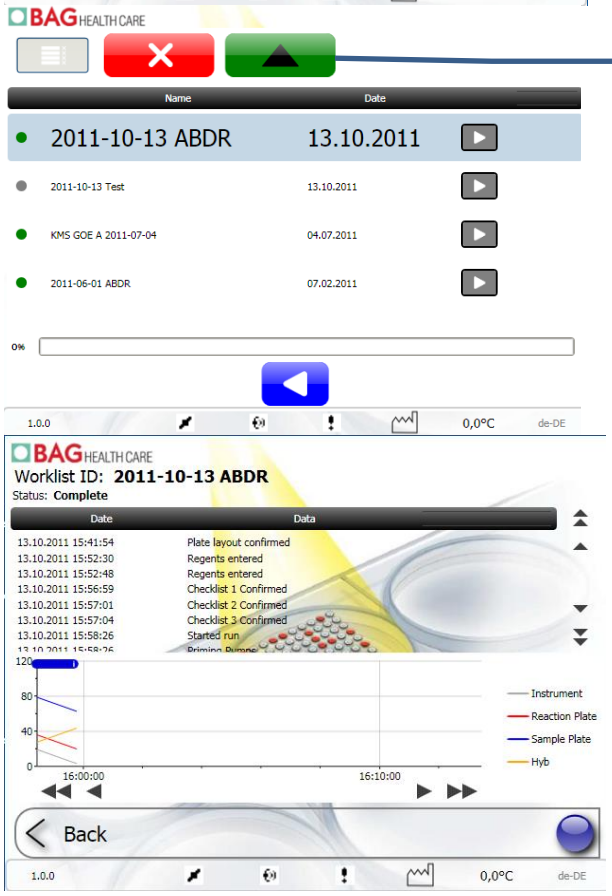

BAG HEALTH CARE
Imaging Worklist W-2012-12-14
14.12.2012 15:22 Imaging well E1
14.12.2012 15:22 Imaging well D1
14.12.2012 15:22 Imaging well C1
14.12.2012 15:22 Imaging well B1
14.12.2012 15:22 Imaging well A1
19,8°C

23. When the assay is finished the wells are photographed.



24. Press **OK** and **Close** .
The starting screen will appear.
Press **Worklists**.

25. After the imaging the worklist appears in the list of worklists. Press the **More** button.



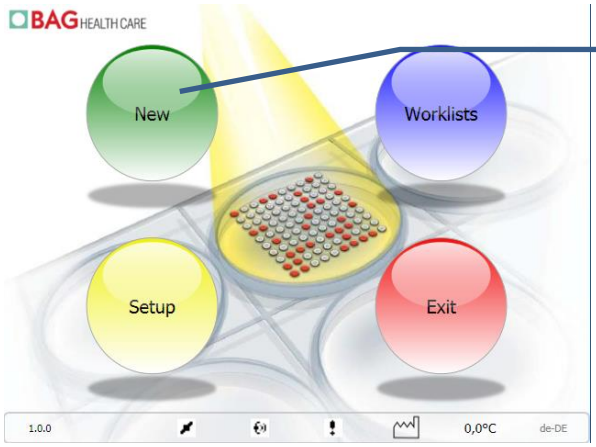
26. The highlighted worklist is exported to a USB stick by pressing the **Export** button and transferred to HISTO MATCH for interpretation. Networked machines can be accessed directly using HISTO MATCH.

Pressing the grey arrow besides the worklist name opens a window with the event log of the array.

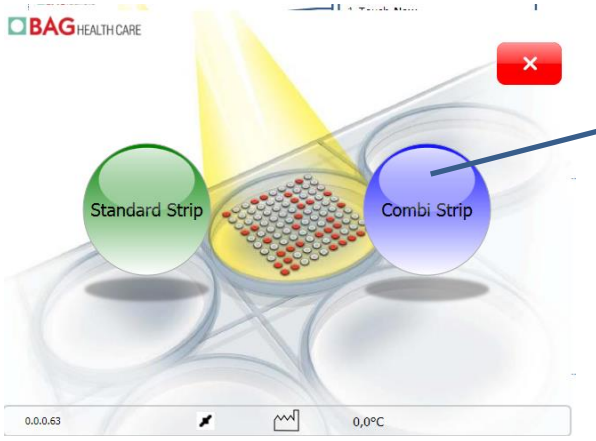
It is also possible to view the temperature graph here.

For interpretation of the results please refer to the HISTO MATCH user manual.

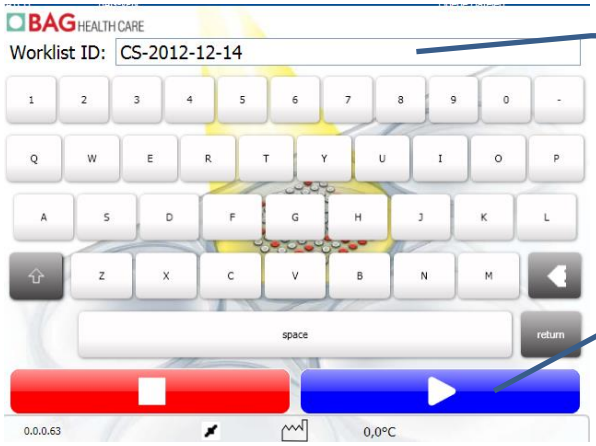
7.1.2 Creating a combistrip worklist



1. Touch **New.**

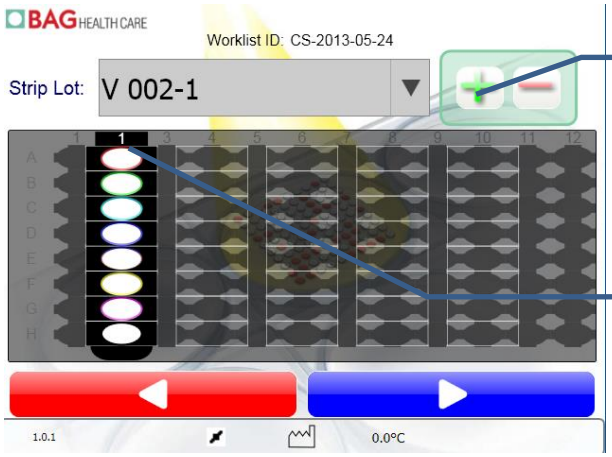


2. Chose **Combi Strip.**



3. Use keyboard to enter Worklist ID or use the default Worklist ID given by the software.

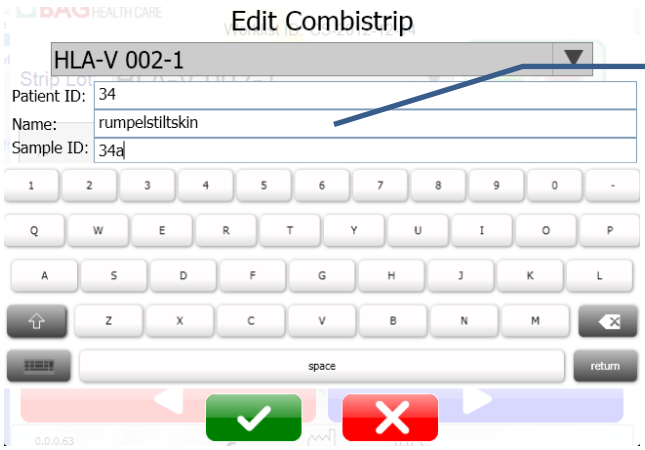
4. Press **Next.**



5. You can enter a strip directly by reading the barcode. Alternatively you can chose a lot from the dropdown list and touch the **Add Strip** button.

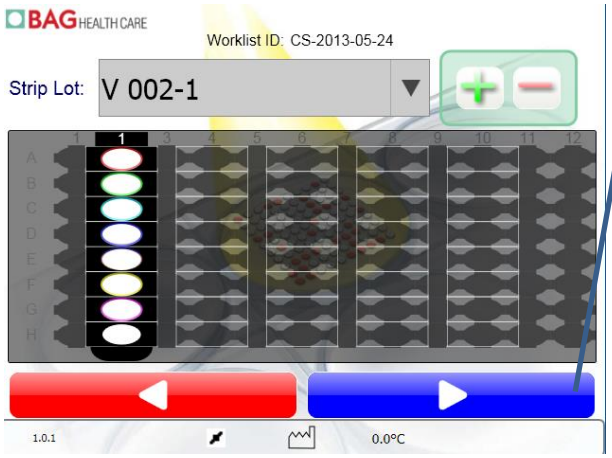
6. You can enter patient data for the test by clicking on the numbers at the top.

(new screen)



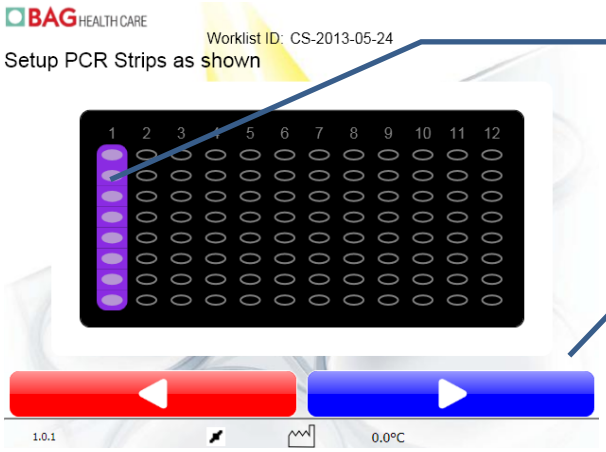
7. Click into the data fields and enter patient information with the on screen keyboard.

Press **Save** to save it or **Delete** to discard the changes.



8. Press **Next**.

(new screen)



9. Set the PCR strips with the amplicons in the heater block as indicated in the diagram.

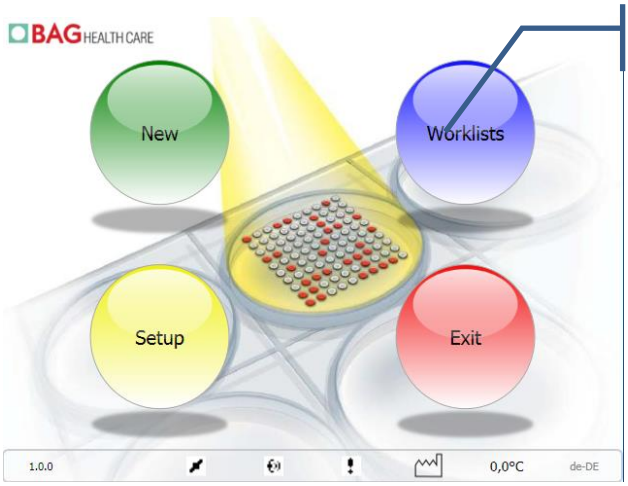
10. Press **Next**.

(new screen)

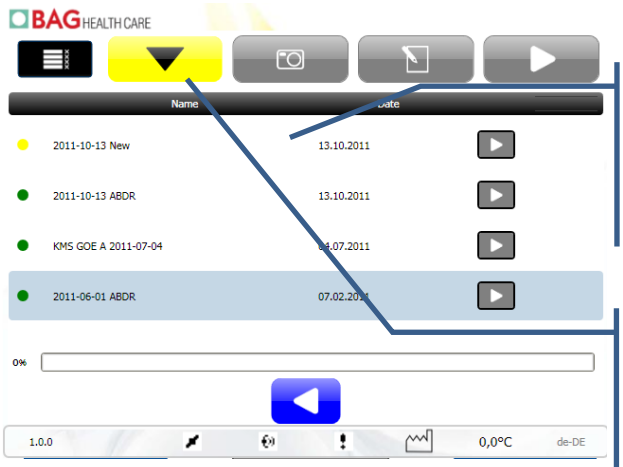
Continue with step 12 of chapter 7.1.1 of this manual.

7.1.3 Importing a standard worklist from HISTO MATCH

For information on how to create a worklist in HISTO MATCH please refer to the HISTO MATCH Software Manual.



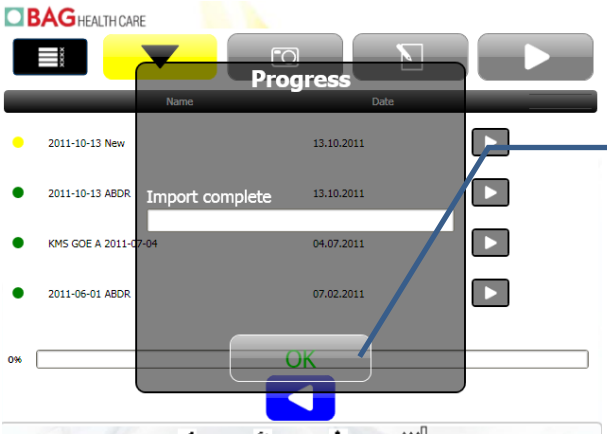
1. Touch **Worklists.**



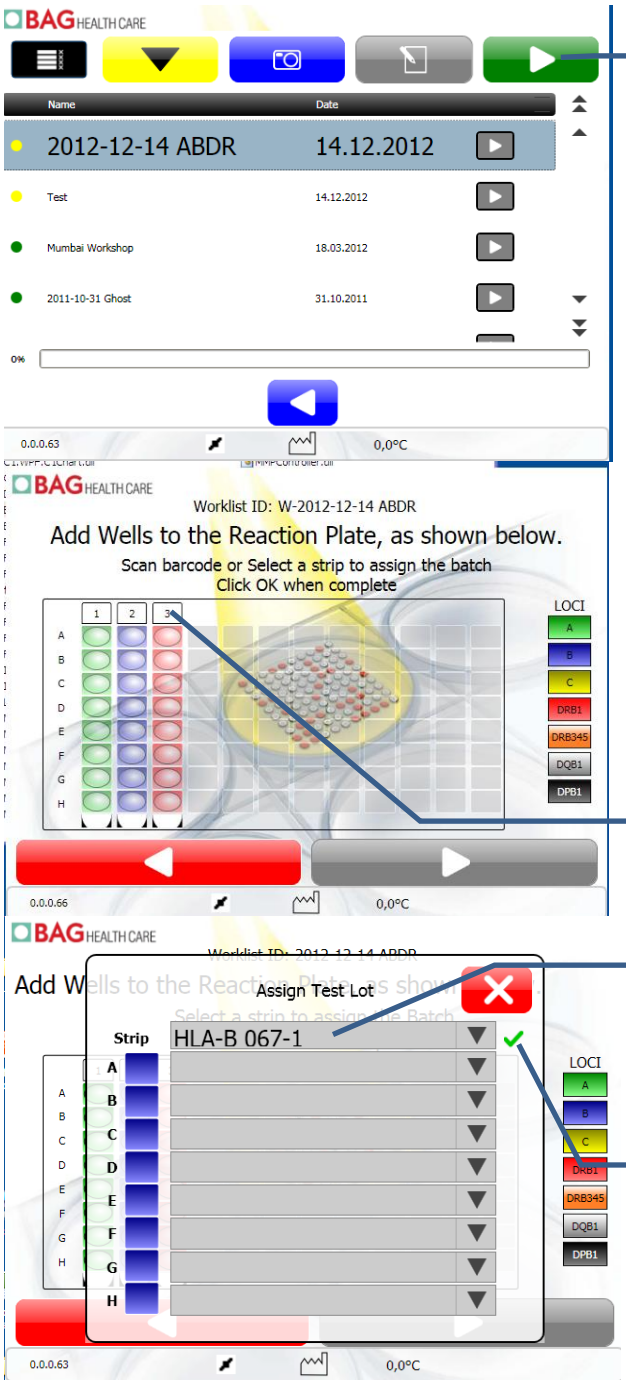
2a. Worklists sent from HISTO MATCH via Network will appear in the worklist screen and can be processed directly.

2b. Insert USB Stick and click **Import**. The worklist will appear in the list ready to be processed.

If only one worklist is imported from a stick you can directly proceed with step 5.



3. Click **OK.**



4. Highlight the worklist to be run and press **Start.**

5. Strip lots can be barcoded directly in this screen. This assigns the barcoded lot to the next wells (1 strip at a time), wells are faint when un-assigned, and then flash when assigned. If an incorrect strip locus is entered a warning is displayed, and batch is not assigned, the batches **must** be assigned in order.

6. Alternatively, enter the strip lot by clicking on the number at the top of the strip.

7. Enter the strip lot number for single wells by using the barcode reader, or by choosing one from the dropdown list.

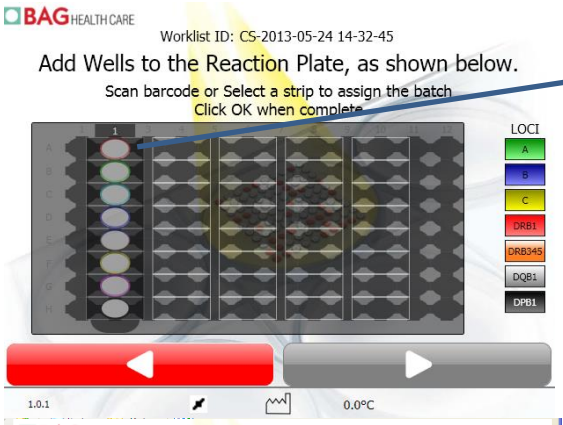
8. Pressing the green tick mark selects the chosen lot for the complete strip.

9. Press **Close and Save** when finished.

Continue with step 12 in chapter 7.1.1 of this manual.

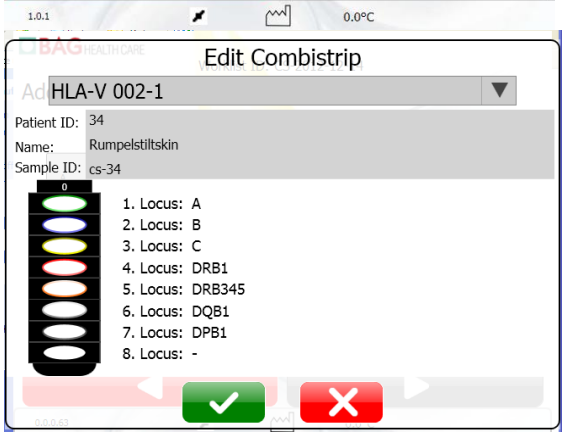
7.1.4 Importing a combistrip worklistfrom HISTO MATCH

Importing a combistrip worklist from HISTO MATCH works the same as importing a standard work-list. After step 4 from chapter 7.1.3 continue as follows:

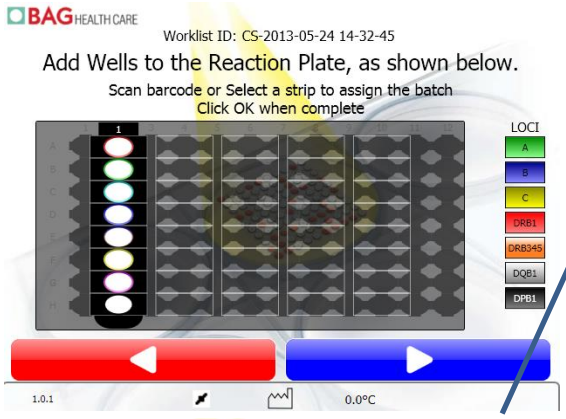


(new screen)

5. Enter the strip lot by either barcoding it directly from this screen or by clicking on the number at the top of the screen.

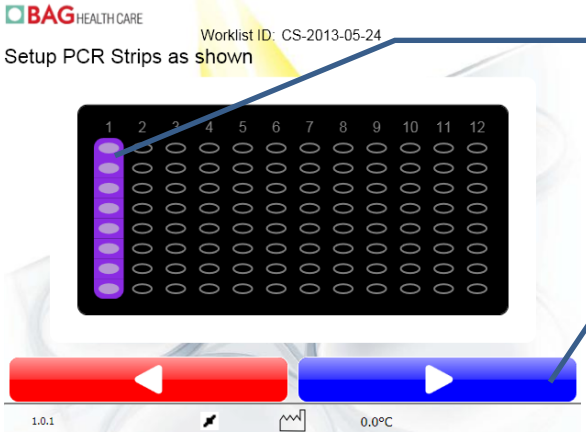


6. Here you can chose a strip lot from the dropdown list. You can also view patient information here. Press **Save** when finished.



(new screen)

7. Press **Next.**



8. Set the PCR strips with the amplicons in the heater block as indicated in the diagram.

9. Press **Next.**

Continue with step 12 of chapter 7.1.1 of this manual.

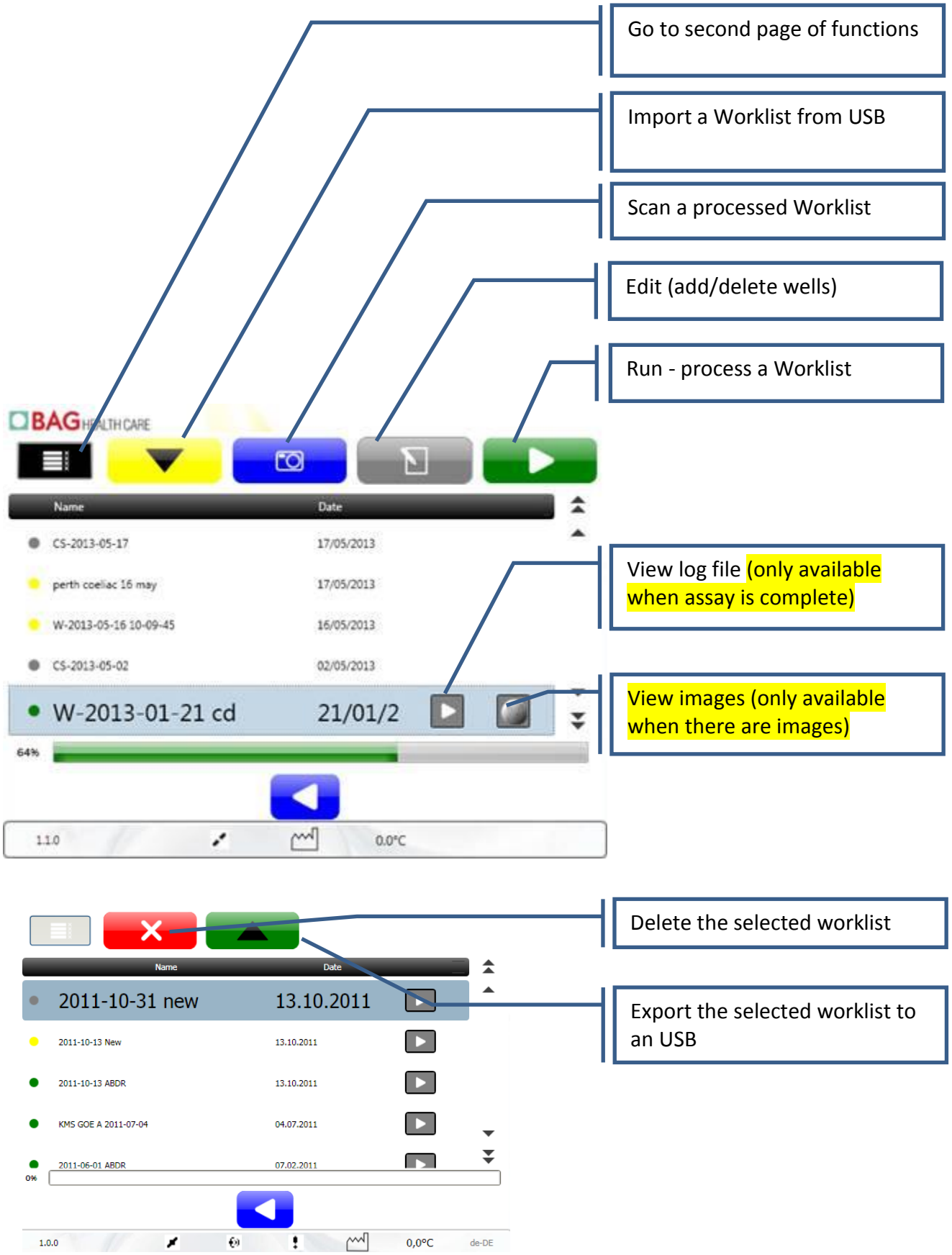
7.2 Assay Protocol

The following table indicates the steps performed on the MR.SPOT® Processor. During the run the current status of the assay is displayed on the touch screen.

Step	Details
1	PCR Plate Heated Add 200 µl block buffer to each test well and incubate with shaking for 5 minutes Start hybridisation buffer pre-warming (30°C)
2	Aspirate block buffer in reaction plate
3	Add 100 µl pre-warmed (at least 30 °C) hybridisation buffer to PCR plate
4	Mix and transfer 100 µl hybridisation buffer/amplicon from PCR plate to each test well
5	Incubate and shake at 50°C for 15 minutes (adding 2.5 minute for plate to reach 50°C)
6	Cool reaction-plate
7	Aspirate hybridisation buffer
8	Add 200 µl stringency wash buffer to each test well mix (5 seconds) and aspirate Repeat a further two times
9	Add 100 µl diluted conjugate to each test well
10	Incubate and mix at room temperature for 15 minutes
11	Aspirate diluted conjugate
12	Add 200 µl TBS buffer to each test well, mix and aspirate Repeat a further two times
13	Add 100 µl substrate to each test well and cover
14	Incubate and mix at room temperature for 15 minutes
15	Add 100 µl H_20 to the well and aspirate diluted substrate
16	Add 200 µl H_20 to each test well
17	Shake reaction-plate for 10 seconds
18	Aspirate H_20
19	Heat to 51. 7°C for 8 minutes to dry well (liquid handling position)
20	Photograph results in the back of the instrument

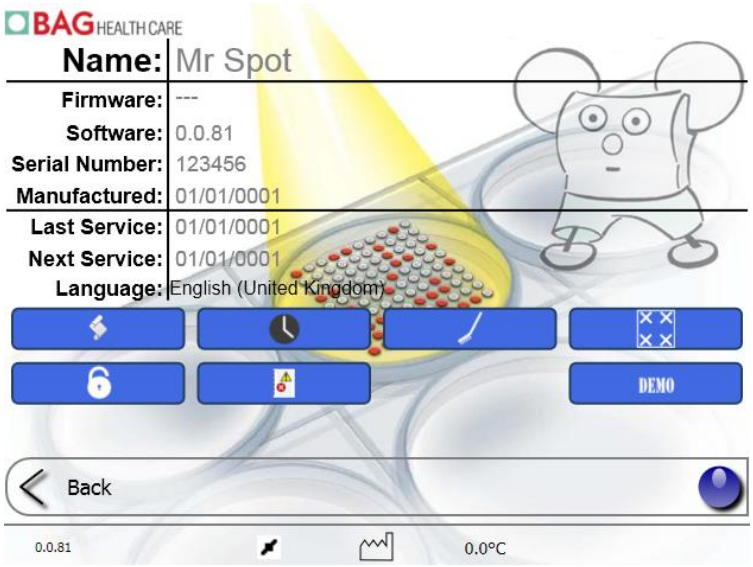
7.3 Worklist Management

The image below shows the different functions of the worklist management screen.



7.4 Setup

The Setup Screen offers different functions for settings and maintenance of the MR.SPOT® Processor. Functions available on this screen are meant for the user of the instrument. Regular maintenance services must be performed by trained personnel only and the functions necessary to do this will only be available to service engineers. For further information please refer to chapter 9 “General Maintenance” of this manual.



View installed programs and update programs (chapter 7.4.1).

View the service history (services can be entered here by the service engineer as well).

Run Wash Program (see chapter 7.4.2).

Run Screen calibration program. This may be necessary if the touch screen image is not in the center e.g. after transport of the instrument.

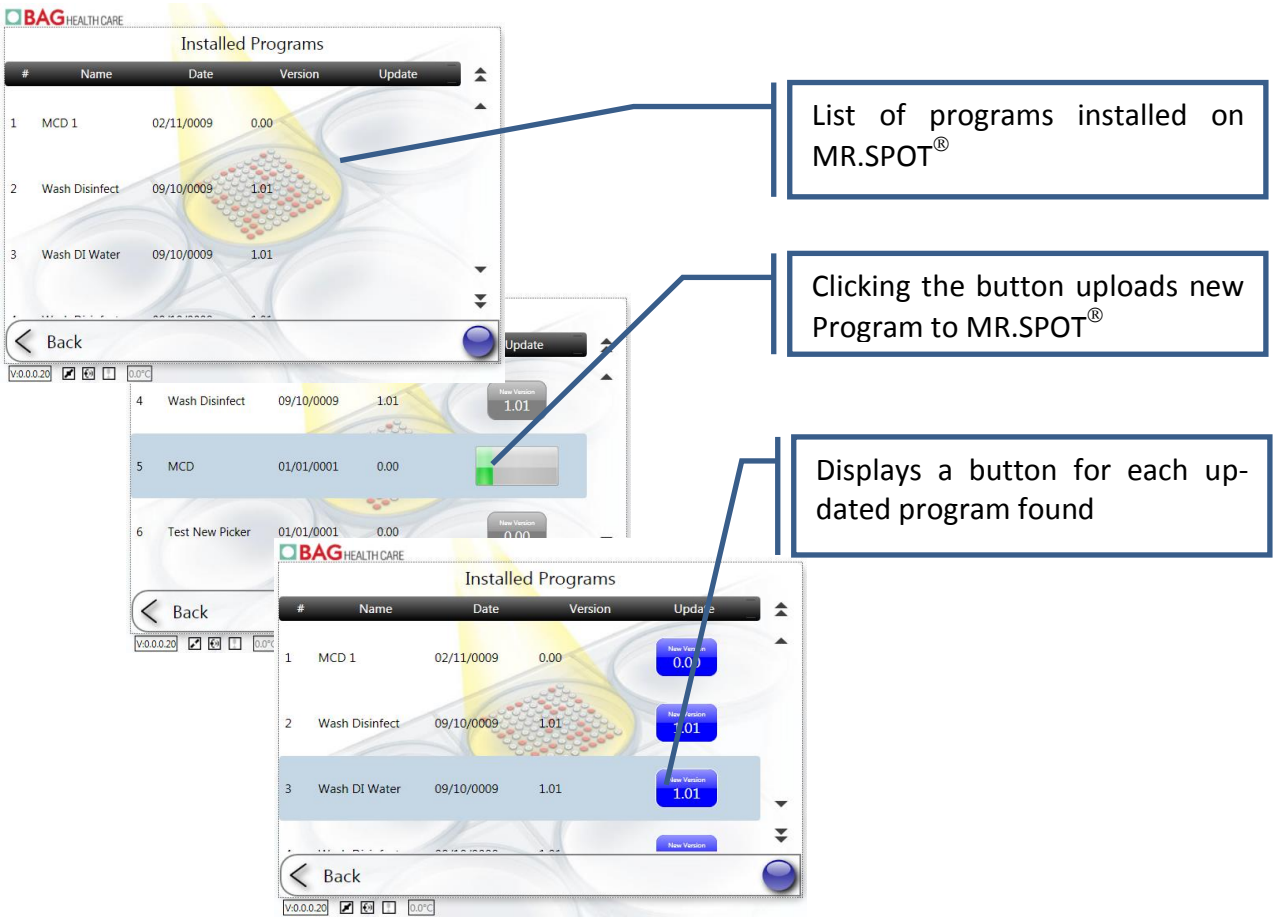
Show overlay dialog. This enables and disables the system protection for software updates.

Export Windows Event Log to USB, a USB stick should be inserted before selecting this.

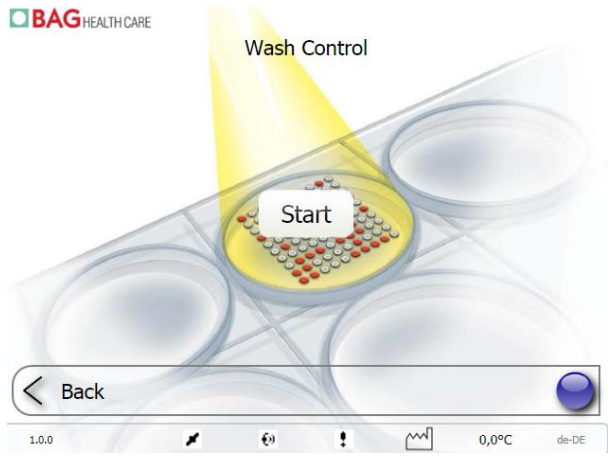
Toggle between demo mode and regular mode. The demo mode has all incubation times reduced to a few seconds and should only be used for service or demonstration purposes. This icon turns red if the demo mode is switched on.

7.4.1 Update and install programs

From the program screen new programs or program updates can be loaded onto MR.SPOT®. Programs and program updates are read from an USB stick.

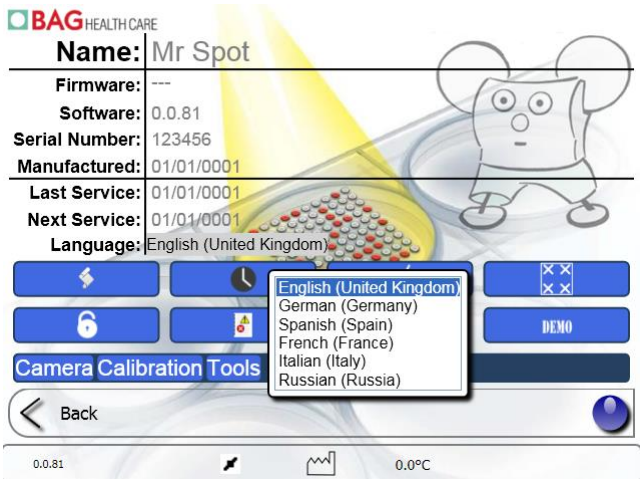

BAG HEALTH CARE
Installed Programs
Name Date Version Update
1 MCD 1 02/11/0009 0.00
2 Wash Disinfect 09/10/0009 1.01
3 Wash DI Water 09/10/0009 1.01
Back
Update
4 Wash Disinfect 09/10/0009 1.01
5 MCD 01/01/0001 0.00
6 Test New Picker 01/01/0001 0.00
List of programs installed on MR.SPOT®
Clicking the button uploads new Program to MR.SPOT®
Displays a button for each updated program found

7.4.2 Wash Program



The Wash Program allows cleaning all lines of the MR.SPOT® Processor. Press **Start** and follow the instructions on the screen. It is recommended to run a disinfection wash every three months. Disinfectants like Virkon®, 1% Chloros® or 1% bleach (natriumhypochloride) can be used for the disinfection run.

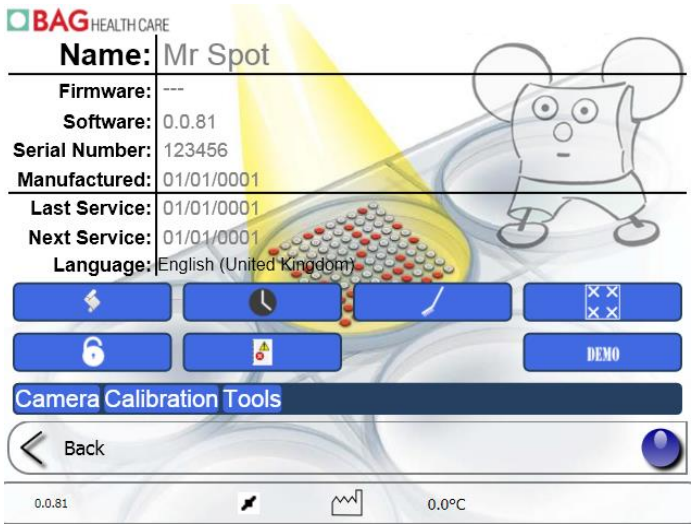
7.4.3 Language switch



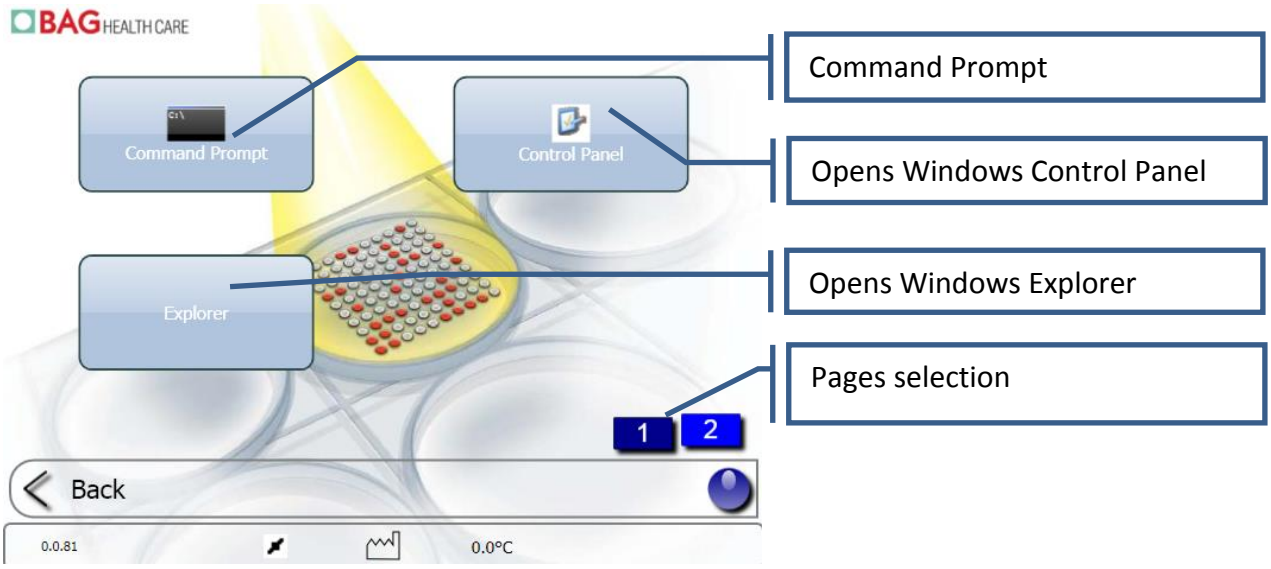
Clicking on the language field opens a drop down list with the languages available.
Choosing a language immediately switches the language shown on the touchscreen.

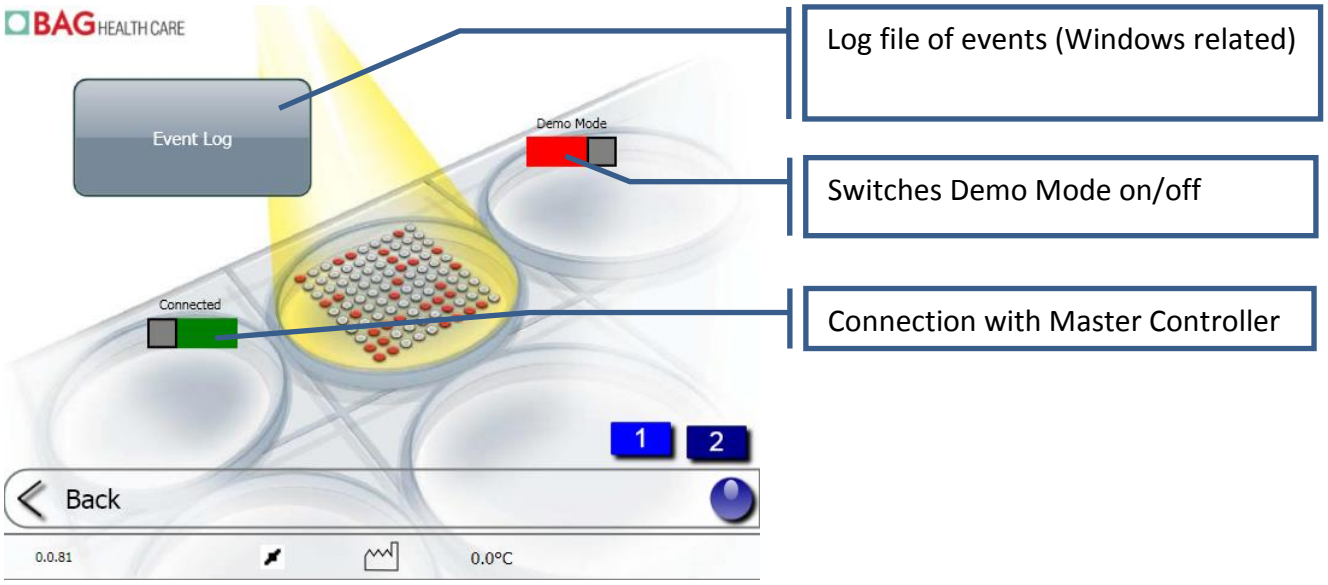
7.5 Fusion tools for maintenance and service

The Fusion tools for maintenance and service are only visible with the tools module that is available to service engineers. This module has to be saved on an USB stick and the MR.SPOT started with the stick inserted.
The setup screen will look like this then:

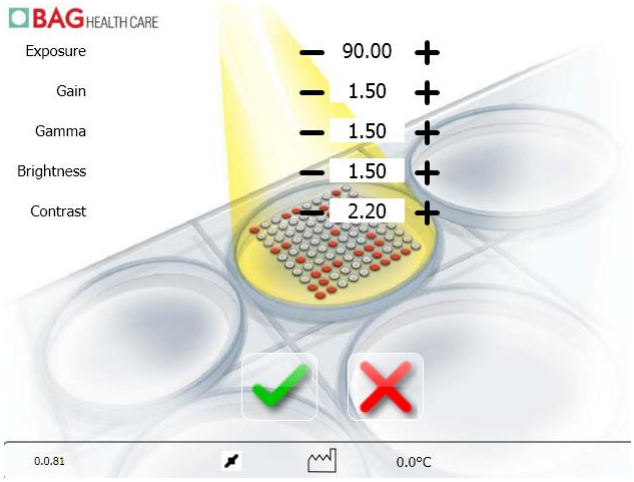


7.5.1 Setup Tools





7.5.2 Camera Settings

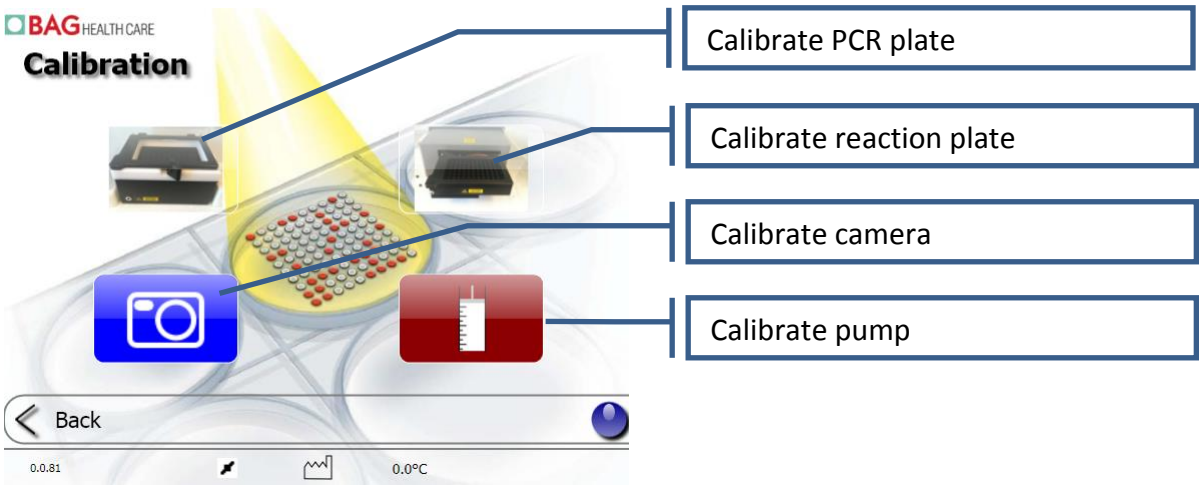


After a run is finished the results are scanned by imaging all single wells. The Camera Settings allow adjusting Exposure, Gain, Gamma, Brightness and Contrast.

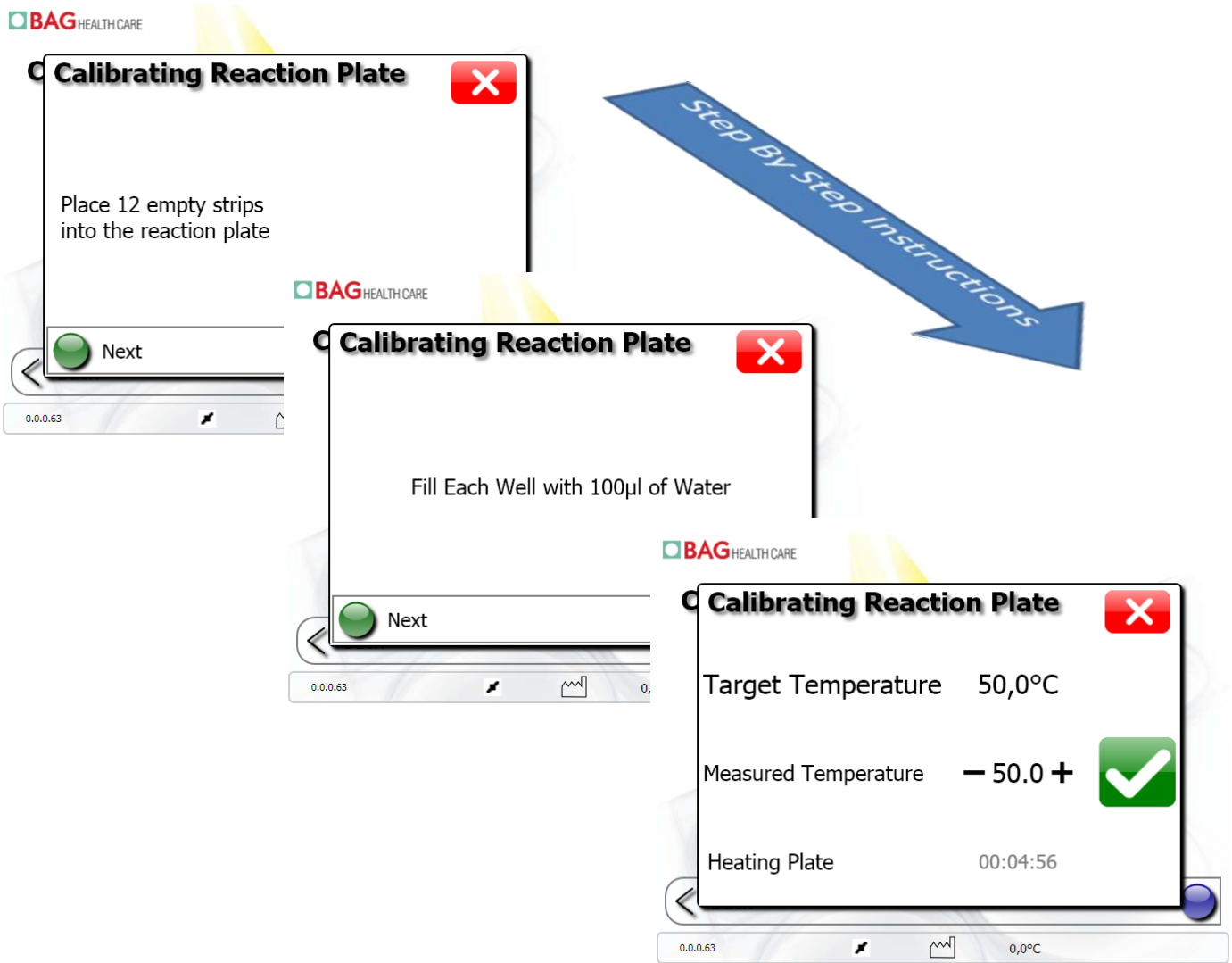
These settings should not be changed without consulting a service engineer !

7.5.3 Calibration

This screen allows to perform the on-screen calibration of PCR plate, reaction plate, pump and camera. Calibrations should only be done by trained service engineers !



To perform calibration, follow the instructions on the screen.



8 TROUBLESHOOTING

8.1 Troubleshooting Guide

If you encounter difficulties with the instrument the simple guidelines below may help you resolve them. The information you gain from these observations will also help qualified service engineers return the instrument to full working order as quickly as possible.

8.2 Visual Inspection

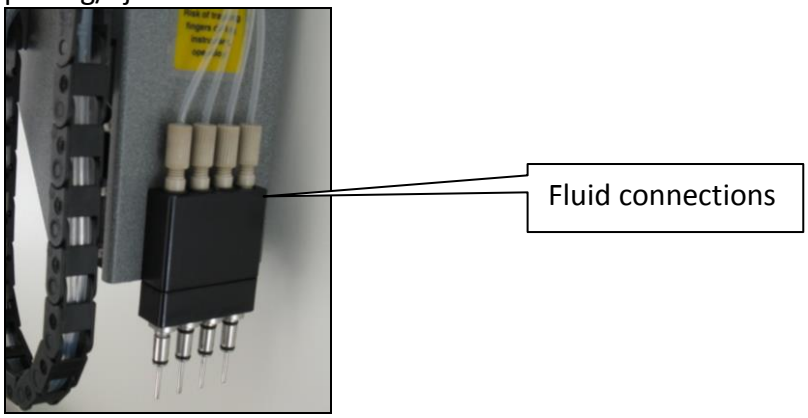
A good visual inspection of the instrument prior to switching it on can sometimes reveal problems or potential problems. Performing the following simple checks will help determine the condition of the instrument.
Check for any signs of obvious damage. With the instrument switched OFF, raise the main cover, and inspect the base of the instrument for any spillages or obstructions that will prevent the accessories from resting flat on the instruments base. Remove all the accessories from the base and clean with a lint free cloth.

8.3 Mechanics

Ensuring that the tip picking/ejection system is in the HOME position, move the X and Y-axis by hand to ensure that there are no obstruction. If obstructions are encountered, look for mechanical obstructions, such as loose screws.
Ensure that the aspirating probes are clean and in good condition. Gently clean each tip with an alcohol wipe. The probes should be straight, if for some reason they have been bent, then a qualified engineer should replace them.
Ensure that the PCR holder is clean, and that the clamping lid is working correctly. Also check the reaction plate lid for any sign of damage. It's important that both lids are able to close properly to avoid any problems during the assay.

8.4 Fluidics

Check for any damage to the tubing, and ensure that there are no kinks visible along the 'Y' and 'X' axis, which could affect the liquid handling. Pay particular attention to the connections at the tip picking/ejection mechanism.



If no problems are encountered during visual inspection, the instrument can be switched on. If problems are encountered during visual inspection, these must be rectified prior to switching the instrument on; otherwise further damage may be done to the instrument.

8.5 Initialisation

The following initialisation sequence of events should occur when the instrument is switched on:

(1) The aspirating needles should move upwards to its 'HOME' position.

(2) The arm should move towards the back of the instrument to its 'HOME' position.

(3) The X-axis should move left to its 'HOME' position.

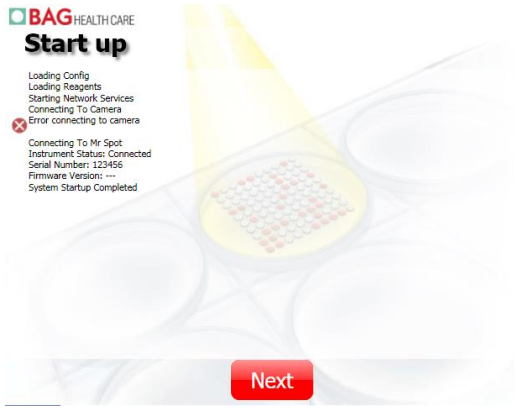
(4) The reaction plate should move outwards from the incubation chamber.

(5) The green light (LED) at the front left hand side of the instrument should be ON.

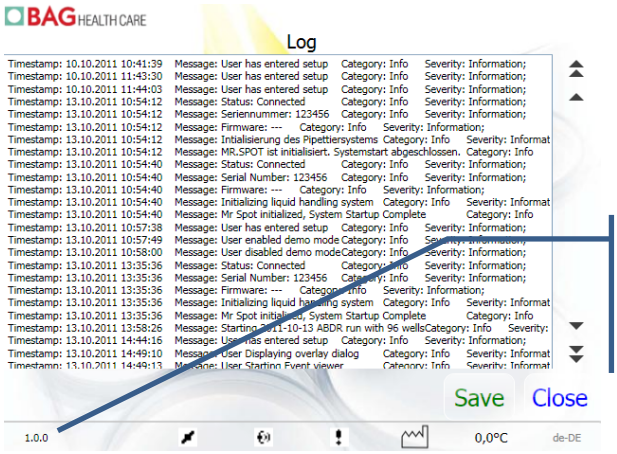
(6) The Touch Screen Display to the left of the instrument should be ON.

If the instrument fails to perform any or all of these tasks, then there is a fault, which needs to be rectified. Please contact your local representative or e-mail service@bag-healthcare.com .

8.6 Error messages



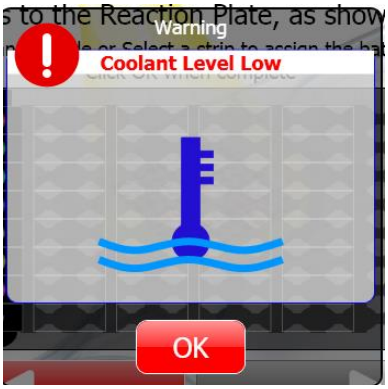
If there are any problems during the start up process, a window with the start up protocol and the relevant error messages will appear. Depending on the messages you can decide to proceed anyway with **Next** or to call for technical support to remove the error.



If further information is needed press **Next** and then press the version number in the lower left corner of the start screen .

8.7 Coolant level warning

If the coolant level for cooling the reaction plate is low the following warning will come up:



It will appear when you start the MR.SPOT and every time before you try to start a run. If there is not enough coolant the reaction plate will not be cooled fast enough, resulting in false negative reactions**. Please fill up the coolant or contact your local representative to do so !**
You will be able to perform up to 10 more runs before the results will be affected after the warning has appeared the first time.

9 ROUTINE MAINTENANCE

9.1 Inspection

It is recommended that the following Routine Maintenance be carried out by trained personnel on a 12 monthly basis.

Check for any signs of obvious damage. With the instrument switched OFF, raise the main cover, and inspect the base of the instrument for any spillages or obstructions that will prevent the accessories from resting flat on the instruments base. Remove all the accessories from the base and clean with a lint free cloth.

Ensuring that the tip picking/ejection system is in the HOME position, move the X and Y-axis by hand to ensure that there is no obstruction.

Clean the aspirating needles with an alcohol wipe, and ensure that there is no damage to the needles.

Replace all the accessories on to the base and run the instrument with D.I. Water.

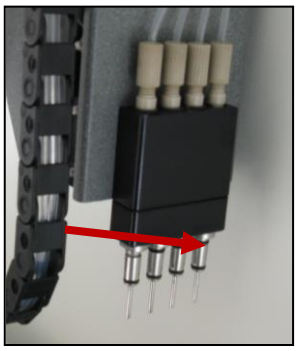
Running the Instrument with Water:

- Select number of sample to be 16.
- Position an appropriate number of tips into the tip rock holder.
- Run a short test assay, and ensure that the initialisation is functioning correctly and that there are no obstructions.
- Ensure that tip picking and ejection system is functioning correctly.
- Observe the operation of the reaction plate, and ensure that it moves in and out of the incubation chamber without any obstructions.
- Ensure that the reaction plate shaking mechanism is working.
- Ensure that the tilting mechanism is functioning correctly.

9.2 Calibration

Refer to your local representative.

9.3 Greasing of O rings



It is strongly recommended that the black o-rings on the aspirating needles are lubricated with silicone grease (provided with the machine) once a month by the user. Place a small (1 mm) blob of grease on each o-ring. Manually place a 200 or 1000 ul tip on the probe, and rotate tip until grease is evenly spread across the o-ring. Repeat for all 4 probes. Discard tip; and then use a small cloth to clean all excess grease from the metal parts on the probes, ensuring that no grease is left on the metal parts, only the o-rings.

10 LIMITED WARRANTY

Please note the serial number of the MR.SPOT® Processor (found on the back of the instrument) below for future reference.

SERIAL No. …….

Warranty

BAG Health Care GmbH warrants that each product described herein will be free from defects in materials and workmanship for a period of one year from the date of delivery. BAG Health Care GmbH agrees, as its sole responsibility under this limited warranty, and upon prompt notice of the defect, to repair or replace any product found to be defective within the warranty period.

The limited warranty is not applicable to: (1) abnormal wear and tear (2) abuse, unreasonable use, improper installation, mistreatment, or neglect (3) damage caused by equipment or system with which the product is used (4) damage caused by modification or repair not made or authorised by BAG Health Care GmbH, or (5) theft, vandalism, fire, water or other peril. Product may not be returned without proper authorisation from BAG Health Care GmbH. Cost of transportation, removal, or reinstallation of the equipment will be paid by the purchaser. This warranty and the remedies set forth herein are exclusive and in lieu of all other express or implied (including any implied warranties or merchantability or fitness for a general purpose), and no other representations or claims shall be binding on or obligate BAG Health Care GmbH in any way. In no event will BAG Health Care GmbH be liable for any special, incidental, or consequential damages resulting from use or malfunction of this product or the equipment or system with which it is used, loss of revenue, or cost of replacement of goods.

11 TECHNICAL SUPPORT

For all technical support and assistance, contact:

BAG Health Care GmbH
Amtsgerichtsstraße 1-5
35423 Lich
Germany

Tel: +49 (0)6404 925 125
Fax: +49 (0)6404 925 421

Web: www.bag-healthcare.com
E-mail: service@bag-healthcare.com

Only by BAG Health Care GmbH or associated trained service personnel may authorise repairs and servicing be carried out.

For further details of instrument or to arrange for training to be given on the instrument, contact BAG Health Care GmbH at above address.

Instructions for Use in other languages see:

http://www.bag-healthcare.com/en/Diagnostika/Downloads/

12 EU DECLARATION OF CONFORMITY

The MR.SPOT® processor conforms with the protection requirements of Council Directive 89/336/EEC, relating to Electromagnetic Compatibility by application of the following EMC standards.

BS EN 61326:1998, Electromagnetic Compatibility – Electrical Equipment for measurement, Control and Laboratory use. Emission and Immunity standard.

The basis on which Immunity standards are being declared: -
IEC1000-4-2 Electrostatic Discharge
IEC1000-4-3 Radio Frequency Electromagnetic Field
IEC1000-4-4 Electrical Fast Transients

We are NOT currently declaring compliance with the Low Voltage Directive 72/23/EC.

The MR.SPOT® processor conforms with the requirements of EU Directive 98/79/EC on in-vitro diagnostic medical devices.

Certificates are available on request – contact service@bag-healthcare.com.

13 APPENDIX

Appendix I: List of Typing Kits the MR.SPOT® Processor can be used with

Name	REF
HISTO SPOT® A 4D	726010
HISTO SPOT® B 4D	726020
HISTO SPOT® C 4D	726030
HISTO SPOT® DRB1 4D	726040
HISTO SPOT® DRB3/4/5	726045
HISTO SPOT® DQB1 4D	726050
HISTO SPOT® DPB1	726060
HISTO SPOT® DPB1	726061
HISTO SPOT® On-Call Typing Kit	726070
HISTO SPOT® Coeliac Disease	726071
HISTO SPOT® Reagent Kit	726098

Appendix II: Synopsis of Symbols used in manual & on instrument

Symbol	Colour	Publication	Description	Placement
	Symbol & Out-line: Black	IEC 60417 – 5032	Alternating Current	Instrument Serial Label
	Symbol & Out-line: White	IEC 60417 – 5007	On (Supply)	Inlet Filter
	Symbol & Out-line: White	IEC 60417 – 5008	Off (Supply)	Inlet Filter
	Background: Yellow Symbol & Out-line: Black	IEC 60417 – 5032	Caution, Hot Sur-face	On Heater Plate
	Background: Yellow Symbol & Out-line: Black	IEC 60417 – 5007	Caution, Risk of Danger	On Waste Station On Control Panel near Red LED – Symbol & Outline: White, no BG colour

Appendix III - MR.SPOT® Processor- INSTALLATION CHECKLIST

INSTRUMENT SERIAL NUMBER

CUSTOMER NAME:	
ADDRESS:	
TELEPHONE NUMBER:	
FAX NUMBER:	
E-MAIL ADDRESS:	

Did the MR.SPOT® processor arrive in good condition? Yes No

If no, provide details:

Were the following accessories present:

Touch Screen	Yes		No	
Touch Screen VGA Cable	Yes		No	
Touch Screen USB Cable	Yes		No	
Touch Screen Mounting arm and screws and tools	Yes		No	
Spare fuses 5A (pack of 2)	Yes		No	
Reagent Trough	Yes		No	
250 ml D.I. Water Bottle	Yes		No	
250 ml square bottle for wash solution	Yes		No	
Bottle Holder	Yes		No	
Tip Rack Holder	Yes		No	
Waste Tip Basket	Yes		No	
Priming/Waste Trough with Lid	Yes		No	
Hybridisation Trough	Yes		No	
Mains Lead	Yes		No	
Barcode reader	Yes		No	
User Manual on CD	Yes		No	
Set of dummy test strips with 16 single clear wells	Yes		No	

Installation CD for HISTO MATCH Software	Yes		No	
Spare Set of 4 O-rings	Yes		No	
Silicone grease syringe	Yes		No	

Did the MR.SPOT® processor initialise correctly? (refer to chapter 8.5 in User Manual) Yes ☐ No ☐

If no, provide details:

Computer name of MR.SPOT for network connection:

Any other comments:

Representative Name:	
Representative Address:	

Representative Signature:		Date:	
Customer Signature:		Date:	
Customer Print Name:		Position:	

Customer to retain original copy.
Distributor must send copy to:
BAG Health Care GmbH, Qualitätskontrolle, Amtsgerichtsstraße 1-5, 35423 Lich, Germany.

Appendix IV – DECONTAMINATION CERTIFICATE

Institute Name _____

Make of Instrument _____

Model Number _____

Tick*

☐ This equipment has not been used in an invasive procedure or been in contact with blood, other body fluids or pathological samples. It has been cleaned in preparation for inspection, service or repair.

☐ This equipment has been cleaned and decontaminated.
The decontamination method is outlined below:

_____

_____

☐ This equipment could not be decontaminated. The nature of risks and safety precautions to be adopted are as follows:

_____

_____

_____

Signed: _____ Date: _____

Position Held: _____

Full Official Address: _____

_____

Telephone No: _____